

Галеника а.д. Београд

Батајнички друм бб, Земун

КОНКУРСНА ДОКУМЕНТАЦИЈА

за набавку добара

Опрема и увођење система за серијализацију

ТЕНДЕРСКИ ПОСТУПАК

набавка број 144/2016

Београд, Новембар 2016. године

ОПШТИ ПОДАЦИ О НАБАВЦИ

1. Подаци о Наручиоцу:

Галеника а.д. Београд
Батајнички друм бб, Београд,
www.galenika.rs

2. Врста поступка

Тендерски поступак – тендерски поступак, у складу са Правилником о набавци добара, услуга и радова у акционарском друштву Галеника а.д. Београд .

3. Предмет набавке

Предмет набавке је набавка добара.

4. Циљ поступка

Поступак набавке спроводи се ради закључења уговора.

5. Рок за доношење одлуке о додели уговора

Одлука о додели уговора биће донета у року од 8 дана, од дана пријема понуда.

6. Контакт

Лице за контакт: Ана Томић, е-mail: atomic@galenika.rs
Зоран Јовановић, е-mail: zjovanovic@galenika.rs

**ПОДАЦИ
О ПРЕДМЕТУ НАБАВКЕ**

1. Опис предмета набавке

Предмет набавке је набавка добара – Опрема и увођење система за серијализацију

2. Врста и опис предмета набавке саставни је део конкурсне документације.

3. Предметна набавка није обликована по партијама.

УСЛОВИ ИЗ ПОНУДЕ

1. Захтев у погледу рока и начина испоруке добара

Рок испоруке не може бити дужи од 9 месеци од пријема писмене поруџбенице Наручиоца, односно од уплате аванса.

Место испоруке добара је локација Наручиоца: Галеника а.д. Београд – Батајнички друм бб, Београд.

2. Примопредаја

Пријем предметних добара биће дефинисан Уговором након усаглашавања обе стране.

3. Гаранција

Понуђач је дужан да гарантује квалитет, а у складу са техничком спецификацијом тако да обезбеди правилно и несметано функционисање опреме.

4. Рекламација

Уколико Наручилац констатује сметње у функционисању опреме, а које нису могле бити констатоване записником, понуђуч је дужан да о свом трошку омогући несметано функционисање предметног добра, а у гарантном року који не може бити краћи од 12 месеци.

**УСЛОВИ ЗА УЧЕШЋЕ У ПОСТУПКУ НАБАВКЕ
ОБАВЕЗНИ УСЛОВИ**

ИЗЈАВА

Под пуном кривичном и материјалном одговорношћу понуђач _____ **ПОТВРЂУЈЕ** да испуњава услове за учешће у тендерском поступку набавке број 144 за 2016. годину, чији је предмет набавка добара – Опрема и увођење система за серијализацију и то:

1.	Да је регистрован код надлежног органа, односно уписан у одговарајући регистар
2.	Да понуђач и његов законски заступник није осуђиван за неко од кривичних дела као члан организоване криминалне групе, да није осуђиван за кривична дела против привреде, кривична дела против животне средине, кривично дело примања или давања мита, кривично дело преваре
3.	Да му није изречена мера забране обављања делатности, која је на снази у време објављивања односно слања позива за подношење понуда
4.	Да је измирио доспеле порезе, доприносе и друге јавне дажбине у складу са прописима Републике Србије или стране државе када има седиште на њеној територији
5.	Понуђач мора да поседује важећи дозволу надлежног органа за обављање делатности која је предмет набавке.
6.	Да над њим није покренут поступак стечаја или ликвидације, односно претходни стечајни поступак.
7.	Да је поштовао обавезе које произилазе из важећих прописа о заштити на раду, запошљавању и условима рада, заштити животне средине, као и да понуђач гарантује да је ималац права интелектуалне својине.
8.	Да располаже неопходним пословним и финансијским капацитетом.

Потпис овлашћеног лица

М.П.

УПУТСТВО ПОНУЂАЧИМА КАКО ДА САЧИНЕ ПОНУДУ

1. Подаци о језику

Понуда мора бити сачињена на српском језику.

2. Посебни захтеви наручиоца у погледу начина припремања понуде

Понуда се саставља тако што понуђач уписује тражене податке у обрасце који су саставни део конкурсне документације.

Пожељно је да сви документи поднети у понуди буду повезани у целину и запечаћени, тако да се не могу накнадно убацити, одстрањивати или замењивати појединачни листови, односно прилози, а да се видно не оштете листови или печат.

3. Подношење понуде

Понуђач понуду подноси непосредно или путем поште.

Уколико понуђач понуду подноси путем поште мора да обезбеди да иста буде примљена од стране наручиоца до датума и часа одређеног у позиву за подношење понуде.

Понуде се достављају у писаном облику на српском језику у затвореној коверти или кутији, затворене на начин да се приликом отварања понуде може са сигурношћу утврдити да се први пут отвара.

Коверат или кутија са понудом на предњој страни мора имати писани текст „ПОНУДА-НЕ ОТВАРАЈ”, назив и број набавке и партију, а на полеђини назив, број телефона и адресу понуђача. Понуде се достављају на адресу: Батајнички друм бб, Београд.

4. Понуда са варијантама није дозвољена

5. Начин измене, допуне и опозива понуде

Понуђач може у року за подношење понуде да измени, допуни или опозове своју понуду и то непосредно или путем поште.

6. Валута и цена

Цена мора бити фиксна, исказана у динарима или еурима без пореза на додатну вредност.

Ако је у понуди исказана неубичајено ниска цена, Наручилац ће поступити у складу са чланом 51. Правилника о набавци добара, услуга и радова у акционарском друштву Галеника а.д. Београд.

Уколико је понуђач домаће правно лице и искаже цену у понуди у еврима у том случају ће се користити одговарајући средњи курс Народне банке Србије, од датума фактурисања, а уколико је понуђач страно правно лице плаћање се вршити у еврима.

Цена мора да садржи све основне елементе структуре цене, тако да понуђена цена покрива све трошкове које понуђач има у реализацији набавке.

7. Захтеви у погледу начина и услова плаћања

Наручилац се обавезује да ће уговорену цену добара плаћати у законски предвиђеном року након извршене испоруке добара. Биће прихваћено и авансно плаћање. Достављен рачун мора да садржи број и датум закљученог Уговора.

Средства финансијског обезбеђења

Меница за озбиљност понуде

Понуђач је дужан да уз понуду достави бланко сопствену меницу која мора бити евидентирана у Регистру меница и овлашћења НБС. Меница мора бити оверена печатом и потписом од стране лица овлашћеног за заступање, а уз исту мора бити достављено попуњено и оверено менично овлашћење са назначеним износом од 5% од укупне вредности и понуде без ПДВ-а. Уз меницу мора бити достављена копија картона депонованих потписа. Рок важења менице је 30 дана од рока важења понуда. Наручилац ће уновчити меницу дату уз понуду уколико понуђач након истека рока за поднесиће понуда: повуче, опозове или измени своју понуду; понуђач коме је додељен уговор благовремено уговор о набавци не потписе. Наручилац ће вратити менице понуђачима са којима није закључен уговор, одмах по закључењу уговора са изабраним понуђачем.

Уколико понуђач не достави меницу, понуда ће бити одбијена као неприхватљива.

Меница за добро извршење посла

Понуђач коме буде додељен уговор, је дужан да одмах по закључењу Уговора, на име доброг извршења посла, преда меницу за добро извршење посла у висини 10% од вредности уговора са калузулом „без приговора“ или на „први позив“ издату од стране пословне банке изабраног понуђача. Меница за добро извршење посла траје 30 дана дуже од рока одређеног за коначан завршетак посла.

Меница за повраћај авансног плаћања попуњену на износ номиналне вредности предвиђеног аванса, која мора бити евидентирана у Регистру меница и овлашћења Народне банке Србије. Меница за повраћај авансног плаћања издаје се у висини аванса са ПДВ-ом, и мора да траје 3 (три) дана дуже од истека рока важности уговора. Меница за повраћај авансног плаћања мора бити оверена печатом и потписана од стране лица овлашћеног за заступање, а уз исту мора бити достављено попуњено и оверено менично овлашћење – писмо. Уз меницу мора бити достављена копија депонованих потписа који је издат од стране пословне банке коју понуђач наводи у меничном овлашћењу – писму.

Наручилац неће уплатити ниједан износ пре него што прими тражено средство обезбеђења за повраћај авансног плаћања.

Предата меница не може да садржи додатне услове за исплату, краће рокове од оних које одреди Наручилац, мањи износ од оног који одреди Наручилац или промењену месну надлежност за решавање спорова.

Реализација средстава финансијског обезбеђења

Наручилац може да реализује средство финансијског обезбеђења .

8. Заштита података наручиоца

Наручилац ће захтевати заштиту поверљивости података које понуђачима ставља на располагање, укључујући и њихове подизвођаче.

Саставни део конкурсне документације је изјава о чувању поверљивих података.

Лице које је примило податке одређене као поверљиве дужно је да их чува и штити, без обзира на степен те поверљивости.

9. Заштита података понуђача

Наручилац ће чувати као поверљиве све податке о понуђачима садржане у понуди који су посебним прописом утврђени као поверљиви и које је као такве понуђач означио речју „ПОВЕРЉИВО“ у понуди. Наручилац ће одбити давање информације која би значила повреду поверљивости података добијених у понуди.

Неће се сматрати поверљивим докази о испуњености обавезних услова, цена и други подаци из понуде који су од значаја за примену елемената критеријума и рангирање понуде.

10. Додатне информације или појашњења у вези са припремањем понуде

Заинтересована лица могу тражити у писаном облику додатне информације или појашњења у вези са припремањем понуде. Наручилац ће заинтересованом лицу послати одговор у писаном облику и истовремено ту информацију објавити на својој интернет страници.

Питања треба упутити на адресу Галеника а.д. Београд, Батајнички друм бб, Београд-Земун уз напомену „Објашњења – набавка број 144/2016”, чији је предмет набавка добара „Опрема и увођење система за серијализацију”, предајом на писарници наручиоца или на е-маил: atomic@galenika.rs, zjovanovic@galenika.rs

11. Додатна објашњења, контрола и допуштене исправке

Наручилац може да захтева од понуђача додатна објашњења која ће му помоћи при прегледу, вредновању и упоређивању понуда, а може да врши и контролу (увид) код понуђача.

Наручилац може, уз сагласност понуђача, да изврши исправке рачунских грешака уочених приликом разматрања понуде по окончаном поступку отварања понуда.

У случају разлике између јединичне и укупне цене, меродавна је јединична цена.

Ако се понуђач не сагласи са исправком рачунских грешака, наручилац ће његову понуду одбити као неприхватљиву.

12. Критеријум за доделу уговора

Одлука о додели уговора донеће се применом критеријума **најнижа понуђена цена.**

13. Понуде са истом понуђеном ценом

У случају да два или више понуђача понуде исту цену наручилац ће изабрати понуду са краћим роком испоруке.

14. Накнада за коришћење патента

Накнаду за коришћење патената, као и одговорност за повреду заштићених права интелектуалне својине трећих лица сноси понуђач.

15. Обавештење о изабраном понуђачу

Наручилац ће писменим путем у року од највише 5 дана обавестите све понуђаче који су доставили понуду за предметну набавку о изабраном понуђачу.

СПИСАК РЕФЕРЕНТНИХ НАРУЧИЛАЦА

Период: последње три године од дана објављивања

Ред. бр.	Списак референтних наручилаца	Из Предметне или сличне области (опис)
	1	2
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

НАПОМЕНА: - У случају већег броја референтних наручилаца ову табелу и образац бр. 1 – копирати.

Наручилац задржава право да сваку референтну потврду провери директно код издаваоца потврде увидом у спецификацију извршених превода као и провером квалитета истих. У случају сумње у веродостојност потврда, Наручилац задржава право да затражи на увид уговоре и доказе о извршеној услузи у форми рачуна и извода из банке. Само у потпуности доказано искуство ће се прихватити као веродостојно

М.П.

Потпис овлашћеног лица

ОБРАЗАЦ ПОНУДЕ

На основу позива за подношење понуде за набавку добара – Опрема и увођење система за серијализацију број 144/16, дајем понуду како следи:

Понуда број: _____

Датум: _____

Понуђач је дужан да попуни све делове обрасца понуде, у складу са својом понудом, да их потпише и овери печатом

М.П

Потпис овлашћеног лица

ПОДАЦИ О ПОНУЂАЧУ

Пословно име или скраћени назив	
--	--

Адреса седишта	Улица и број	
	Место	
	Општина	
Матични број понуђача		
Порески идентификациони број		
Одговорно лице		
Лице за контакт		
Телефон		
Телефакс		
e-mail:		
Рачун - Банка		

М.П.

Потпис овлашћеног лица

ОБРАЗАЦ ПОНУДЕ

Назив	Количина	Јединица мере	Укупна цена исказана у дин/еур без пдв-а
Опрема и увођење система за серијализацију	1	комад	

Понуђач попуњава све ставке из табеле.

Напомена: Цена из табела обухвата све ставке наведене у техничкој спецификацији.

Начин плаћања _____

Рок испоруке _____ дана

Гарантни рок _____ месеци

Рок за отклањање грешака _____ дана

Укупна цена без ПДВ-а _____ динара

Укупна цена са урачунатим ПДВ-ом _____ динара

М.П

Потпис овлашћеног лица

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1. INTRODUCTION

Subject of this project is to implement the solution of supporting identification of individual folding cartons on the packaging line UHLMANN (UPS 1030 MTI/C2205) in Solid Dosage Forms Plant (hereafter SDFP).

2. PURPOSE

The purpose of this document is to provide a clear and precise list of user requirements for the electronic Serialization solution of SDFP. The essential requirements are detailed within this document and specify the needs for online serialization management, generating random unique serial numbers for printing Data Matrix format (in 2D code) on packaging line UHLMANN in SDFP of Galenika a.d. Beograd company.

3. DEFINITIONS AND ABBREVIATIONS

No	Term	Description
1	AGGREGATION	The process of recording the serial number of a container with serial number of its contents, often referred to as parent/child relationship or serialized container to content relationship
2	BAMCS	Business and Manufacturing Control System
3	BAPI	Business Application Programming Interface
4	BMS	Building Management System
5	CD	Compact disc
6	CE	The CE marking (Conformité Européenne) is the manufacturer's declaration that the product meets the requirements of the applicable EC directives
7	21 CFR part 11	The part of Title 21 of the Code of Federal Regulations that establishes the United States FDA regulations on electronic records and electronic signatures (ERES). Part 11, as it is commonly called, defines the criteria under which electronic records and electronic signatures are considered trustworthy, reliable, and equivalent to paper records
8	cGMP	Current Good Manufacturing Practice
9	CMO	Contract Manufacturing Organization
10	CRM	Customer Relationship Management
11	CS	Control system
12	CSV	Comma-separated values file
13	1D code	One-dimensional barcode
14	2D code	Two-dimensional barcode
15	DMS	Dealer Management Software
16	DPI	Dots per inch
17	DRP	Disaster recovery planning
18	EAN	The EAN-13 barcodes are used worldwide for marking products often sold at retail point of sale. The numbers encoded in EAN-13 bar codes are product identification numbers
19	EDI	Electronic data interchange (EDI) is an electronic communication method that provides standards for exchanging data via any electronic means. By adhering to the same standard, two different companies or organizations, even in two different countries, can electronically exchange documents

20	EHIBCC	In Europe, the standard has been accredited for use by the European Committee for Standardisation (CEN), and is administered by the European Health Industry Business Communications Council (EHIBCC)
21	EPCIS	In computer science, Electronic Product Code Information Services (EPCIS) is a global GS1 Standard for creating and sharing visibility event data, both within and across enterprises, to enable users to gain a shared view of physical or digital objects within a relevant business context
22	ERP	Enterprise Resource Planning
23	EU	European Union
24	EXP	Expiry date
25	FAT	Factory Acceptance Test
26	FDA	Food and Drug Administration
27	FMD	Falsified Medicines Directive (Directive 2011/62/EC)
28	FS	Functional Specifications
29	FTP	File Transfer Protocol
30	GAMP5	Good Automatic Manufacturing Practice is Guide for Validation of Automated Systems in Pharmaceutical Manufacture describes a set of principles and procedures that help ensure that pharmaceutical products have the required quality
31	GDSN	The Global Data Synchronization Network (GDSN) is an internet-based, interconnected network of interoperable data pools and a global registry known as the GS1 Global Registry, that enables companies around the globe to exchange standardised and synchronised supply chain data with their trading partners using a standardised Global Product Classification.
32	GMP EU Anex11	Good Manufacturing Practice - Computerized Systems
33	GS1	GS1 is a neutral, not-for-profit, international organization that develops and maintains standards for supply and demand chains across multiple sectors
34	GTIN	Global Trade Item Number is an identifier for trade items developed by GS1
35	GUI	Graphical user interface
36	GxP	Good x Practice
37	HDS	Hardware Design Specification
38	HMI	Human Machine Interface
39	HP	Hewlett-Packard
40	HTML 5	Mark up language used for structuring and presenting content on the World Wide Web
41	HTTPS	Hypertext Transfer Protocol Secure
42	HW	Hardware
43	IDoc	Intermediate Document
44	IFA	IFA GmbH is an information service provider for the pharmaceutical market and provides information services including economic and legal information for goods sold in pharmacies in Germany.
45	IQ	Installation Qualification
46	ISA-95	International standard from the International Society of Automation for developing an automated interface between enterprise and control systems
47	ISO/IEC 16022:2006 and ISO/IEC 15415:2011	International Organization for Standardization/International Electro technical Commission - Data Matrix bar code symbology specification and Two-dimensional symbols
48	IT	Information Technology
49	JSON	JavaScript Object Notation
50	Kerberos	Computer network authentication protocol that works on the basis of 'tickets' to allow nodes communicating over a non-secure network to prove their identity to one another in a secure manner
51	LAN	Local area network

52	LCD	Liquid Crystal Display
53	LDAP	Lightweight Directory Access Protocol
54	LS	List directory contents
55	MAH	Market authorization holder
56	Mersenne Twister	Pseudorandom number generator
57	MES	Manufacturing Execution Systems
58	MRP II	Manufacturing Resource Planning
59	NFC	Near-field communication
60	OCR	Optical Character Recognition
61	OCV	Optical Character Verification
62	OQ	Operational Qualification
63	OS	Operating System
64	P&V	Print&Verify equipment
65	PC	Personal Computer
66	PDF	Portable Document Format
67	3PL	Third party logistics
68	PLC	Programmable Logic Controller
69	PPN	Pharmacy Product Number
70	PQ	Performance Qualification
71	RFID	Radio frequency identification
72	RS232	Standard for serial communication transmission
73	SAP	Systems, Applications & Products in Data Processing
74	SAT	Site Acceptance Test
75	SDFP	Solid Dosage Forms Plant
76	SDS	Software Design Specification
77	SGTIN	Serialized Global Trade Item Number – The combination of Global Trade Item Number and serial number which uniquely identify item
78	SKU	Stock keeping unit
79	SLA	Service level agreement
80	SOP	Standard operating procedure
81	SSCC	The serial shipping container code (SSCC) is an 18-digit number used to identify logistics units. In order to automate the reading process, the SSCC is often encoded in a barcode, generally GS1-128, and can also be encoded in an RFID tag
82	SSH	Secure Shell
83	SW	Software
84	T&D	Tracking & Dispensing system
85	TCP/IP	Transmission Control Protocol/Internet Protocol
86	TXT	Text file
87	UPS	Uninterruptible Power Supply
98	URS	User Requirement Specification
89	VAP	Validation Protocol
90	VPN	Virtual private network
91	Web API	Application programming interface for either a web server or a web browser
92	WMS	Warehouse management system
93	XML	Extensible Mark-up Language (XML) is a mark-up language that defines a set of rules for encoding documents in a format which is both human-readable and machine-readable
94	XSLT	XSLT (Extensible Style sheet Language Transformations) is a language for transforming XML documents into other XML documents, [1] or other formats such as HTML for web pages, plain text or into XSL Formatting Objects, which may subsequently be converted to other formats, such as PDF, PostScript and PNG

4. SCOPE

This document provides the User Requirements Specification for the Serialization Solution. The scope of the URS document includes detailed description of the requirements.

The main elements of the scope are:

- Applying unique identifier on the finished medicinal products' outer packaging, on a folding carton level;
- The unique identifier is a standard 2D Data Matrix code containing at least product code, batch number, expiry date and a unique randomized serial number;
- The unique identifier is to be reported to a national and/or European repository system;
- At the point of delivery (e.g. by pharmacist to the patient) the product will be verified against the repository database.

5. REFERENCES

5.1 Regulations

- European Parliament and Council Directive 2001/83/EC: The Rules Governing Medicinal Products in the European Union, Volume I, including Annexes.
- DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products (Directive 2011/62/EC Falsified Medicinal).
- Directive 2016/161/EC Safety Features, including Annexes I and II.
- Guidelines for Good Manufacturing Practice (GMP) for Medicinal Products for Human and Veterinary Use: The Rules Governing Medicinal Products in the European Union Volume IV, including Annexes.

5.2 Guidelines

- Good Automated Manufacturing Practice – GAMP5 – Appendix D1, Procedure for the production of a User Requirement Specification
- FDA Guidance for Industry – Part 11, Electronic Records; Electronic Signatures – Scope Application. August 2003.
- GS1 Data Matrix Guideline – Overview and technical introduction to the use of GS1 Data Matrix – Release 2.2.1., July 2015

6. GENERAL REQUIREMENTS

Serialization integrated platform shall include:

6.1 One Print&Verify equipment (P&V)

- 6.1.1 P&V shall be an integral part of the packaging line, downstream the labelling machine and upstream the bundler. P&V first receives a set of work orders from Plant Manager System.
- 6.1.2 In the next step P&V demands unique codes from Plant Manager System according to the selected work order and regime.
- 6.1.3 P&V shall print demanded data: Expiry date, Batch No., Serialization No. human readable on flap on the folding carton.
- 6.1.4 Also, P&V shall print the complete unique Serialization number in the form of a code, 2D, which in case of Galenika consists of:
 - Batch No.

- GTIN:
 - Expiry date:
 - Serial number:
- 6.1.5 The system should be able to verify correctness of human readable data, except in case when human readable data isn't required (if the sum of the two longest dimensions of the pack is ≤ 10 cm).
- 6.1.6 The system should be able to verify if 2D data matrix code is correct.
- 6.1.7 The equipment shall ensure tamper-evident closing of each carton, along with the verification of the closing integrity.
- 6.1.8 The equipment shall ensure transport of single cartons from the upstream machine to the downstream one, i.e. it shall not block the packaging line when the serialization and tamper evident functions are off.
- 6.1.9 Equipment shall be designed in accordance with the cGMP requirements and in compliance with the CE marking requirements. The equipment shall be qualified to comply with the EU and FDA requirements.
- 6.1.10 The machine shall operate in the so-called *Grey Area* of controlled environment. Manufacturing conditions: humidity 30-65%, temperature 18-25°C.

6.2 Plant Manager System for serialization

- 6.2.1 Dedicated instance on shared environment.
- 6.2.2 Switchable to onsite/cloud instancing.
- 6.2.3 Satisfying regulatory requirements.
- 6.2.4 Unlimited number of users.
- 6.2.5 Validation documentation.
- 6.2.6 User and administration manuals.
- 6.2.7 Serbian and English language GUI.
- 6.2.8 Unlimited number of printed labels on single production line.
- 6.2.9 Aggregation supported manually or automatically.
- 6.2.10 Unlimited number of different products per production line.
- 6.2.11 Possibility for implementation unlimited number production line.
- 6.2.12 SW Maintenance and support.

6.3 Integration P&V with Plant Manager System for serialization in one system on Galenika IT infrastructure

7. BASIC REQUIREMENTS FOR P&V

7.1 Technical data

- 7.1.1 In-line operation in the packaging line at capacity about 300 cartons/min
- 7.1.2 Maximum length of P&V is 1500 mm
- 7.1.3 Easy and quick size changeover (no tools needed)
- 7.1.4 Size of the cartons to be processed:
 - L x W x H = 103 x 42 x 39 mm
 - L x W x H = 84 x 34 x 25 mm
- 7.1.5 The equipment shall be designed so as to allow for easy future upgrading for VIGNETTE labelling.
- 7.1.6 The equipment shall be designed so as to allow for easy future upgrading for printing on both sides and on top, by adding new print heads.

7.2 Machine frame

Basic frame

- 7.2.1 Completely closed balcony protective housing of the entire machine.
- 7.2.2 Frame made of aluminium machine building profiles.
- 7.2.3 Doors made of acrylic glass (e.g. Plexiglas).
- 7.2.4 Stable construction with legs to adjust the working height.
- 7.2.5 Electrical Stainless steel cabinet for machine's electric equipment installation.

Conveyor belts

- 7.2.6 Shall to provide transport between upstream and downstream machine
- 7.2.7 Automatic speed synchronization according to the carton dimensions and machine speed.
- 7.2.8 Adjustable side guides based on carton dimensions.
- 7.2.9 Fixed carton guidance provides accurate transportation of cartons in lateral direction, carton perpendicularity according to transport direction and controlled spacing between cartons which are prerequisites for accurate labels application and imprint positioning.
- 7.2.10 Short outfeed conveyor allows controlled transport of cartons from the main conveyor belt onto the conveyor belt of the following device.

Electrical equipment

- 7.2.11 Power supply connection and UPS.
- 7.2.12 Elements for power supply and protection of all components, including electrical equipment for tamper evident labelling.
- 7.2.13 SIEMENS SIMATIC S7 PLCs for controlling all components and integration of equipment in the entire line process.
- 7.2.14 Potential-free relay contacts for signals exchange with an entire line for synchronization of the device with a line.
- 7.2.15 8-port Ethernet switches to connect all components in local area network (PLC controllers, verification systems, printer, computer, etc.).
- 7.2.16 Managing the labelling process through the HMI.
- 7.2.17 Monitoring the labelling process (operating modes, running out/out of labels, warnings and errors display, drives error, etc.) and based on all these data relevant signalization and reports.
- 7.2.18 Service mode for testing and adjustment of the entire tamper evident labels applying.
- 7.2.19 Optical (three colours traffic light) and audible (horn) signalling of the entire plant operation.
- 7.2.20 Each motor shall be controlled by PLC

7.3 Integrated information support for machine managing

- 7.3.1 Integrated HMI (human-machine interface) for managing entire device and all the components from a single location (touchscreen).
- 7.3.2 Industrial class PC with at least 15-inch LCD touchscreen (Siemens, Beckhoff etc.) and installed Windows 7 Embedded.
- 7.3.3 All components of device (PLC controllers, verification systems, printer, computer, etc.) are

connected to the local network, which enables optional connection with remote access in case of troubleshooting, control, configuration and management for complete device and all the components. By assigning remote access rights it enables remote assistance, problem and error locating and total machine maintenance.

- 7.3.4 Built-in PC for managing all processes and all relevant data and events, generating reports, communicating with MES/ERP and visualization of all processes.
- 7.3.5 21 CFR part 11 compliant, complete audit trail etc.
- 7.3.6 Device monitoring (status of all individual subsystems, current capacity of the machine, running out / out of media, integrated display of all the warnings and errors from the individual subsystem, drives error, etc.) and based on all these data relevant signalization and reports.
- 7.3.7 All events shall be recorded in the log file. The entire operation history of the machine and all marking processes can be analyzed in case of any problems.
- 7.3.8 Enter and change data is accessible only to users with correct user rights with their username and password – accessible to different user levels (e.g. operator, technician, technologist, maintainer, administrator).
- 7.3.9 Reports generated in PDF or other formats.
- 7.3.10 Reports shall be developed in accordance with regulatory requirements.
- 7.3.11 Reports saving and printing via Ethernet network (network printer via TCP/IP protocol).
- 7.3.12 Keeping statistics: the number of all/good/ejected cartons.
- 7.3.13 Service mode for testing and adjustment of the entire machine and individual components.
- 7.3.14 All menus shall be in the English language and Serbian language. **(If no Serbian translation is provided, all display messages/texts shall be translated to Serbian by Galenika upon receiving the associated files).**

7.4 Handheld scanner

- 7.4.1 2D cordless handheld scanner for data entering, 2D code checking and optional manual reworks in serialization and aggregation.
- 7.4.2 Data logic Power Scan scanner.
- 7.4.3 Scanner reads 1D and 2D codes.
- 7.4.4 Scanner supports reading and sending multiple codes in one reading.
- 7.4.5 USB interface.
- 7.4.6 Housing for scanner.

7.5 Printing

- 7.5.1 Industrial thermal ink-jet printer for printing on flap of the carton print based upon HP technology.
- 7.5.2 System shall be able to print all standard codes 1D and 2D barcodes on the folding carton (2D data matrix ECC200 according to ISO 16022:2006).
- 7.5.3 The system shall be able to print in human readable form minimum 3 different lines of information (GTIN code, serial number, National reimbursement number) and 2D data matrix onto a specified pack area.
- 7.5.4 Print resolution 600 dpi.
- 7.5.5 A quality of printing need to be rated at least 1.5 in accordance with ISO/IEC 15415:2011.
- 7.5.6 Print speed with 4 text rows and 2D code 60 m/min.
- 7.5.7 Incremental encoder for imprinting synchronization depending on the folding carton transportation speed.

- 7.5.8 LCD display.
- 7.5.9 Device status, warnings and alarms indication.
- 7.5.10 Ethernet, USB, RS232 communication interfaces on outside surface of machine.
- 7.5.11 I/O lines for PLC controller connections.
- 7.5.12 Printing on all porous materials.
- 7.5.13 Printing variable data from databases.
- 7.5.14 Remote access and managing printer through a network.
- 7.5.15 Managing printing integrated directly from the common single machine monitor HMI.
- 7.5.16 Possible to install at least 4 print heads.
- 7.5.17 Software that runs in a separate window in HMI and enables managing folding carton printing process – imprinting, verification, ejection, data logging and statistics.
- 7.5.18 All components for imprinting (printer, camera) to be connected to the local network, which enables the optional connection with remote access in case of troubleshooting, control, configuration and management of complete device and all the components.
- 7.5.19 Centralized monitoring of printing process over a HMI (operating mode, machine status, data for imprinting, integrated display of all the warnings and errors, etc.) and based on all these data relevant signalization and reports.
- 7.5.20 IT support for printing process and verification of printing, with special emphasis on 2D code and variable data in alphanumeric text imprinting.
- 7.5.21 Managing imprinting process through HMI.
- 7.5.22 All relevant data logging.
- 7.5.23 Statistics on printing and printing verification: the number of all/good/ejected folding cartons.

7.6 Camera verification system

- 7.6.1 System configured to verify 2D code and OCR/OCV control of printed text.
- 7.6.2 Managing verification integrated directly from the common single machine monitor HMI.
- 7.6.3 Software for management and administration of the system.
- 7.6.4 Product database including device settings.
- 7.6.5 Control unit with associated software.

7.7 Stand for camera and printer

- 7.7.1 Stand for mounting camera and print head on to the basic machine.
- 7.7.2 Positioning the camera and printer head regarding the folding carton dimensions and desired print position on the carton.
- 7.7.3 Threaded spindles for adjusting camera and print head regarding the carton height and width.
- 7.7.4 Position indicators on each threaded spindle for quick and repeatable position adjustment regarding each product dimensions and preferred adjustments.

7.8 Rejection system

- 7.8.1 Non-verified carton ejection system based on the results of print verification and tamper evident label presence on the carton.
- 7.8.2 Tracking each carton from verification phase to the rejection.
- 7.8.3 Pneumatic ejection (with air nozzle or pneumatic cylinder) of non-verified cartons into the ejection container.
- 7.8.4 Ejection container locked with a key and fulfil control sensor.
- 7.8.5 Ejection execution controlled with an additional sensor.

7.8.6 Alarm and optional cartoner stop in case of multiple consecutive negative verifications.

7.9 Tamper evident labelling

Labeller, 2 pcs:

7.9.1 Automatic tamper evident label applicator.

7.9.2 Label application speed up to 60m/min.

7.9.3 Inner label roll diameter 76mm.

7.9.4 Label size:

- Label width min. 20mm, max. 40mm,
- Label length min. 15 mm and max. 40mm.

7.9.5 Label positioning accuracy + / - 1mm

7.9.6 Longitudinal position of label appliance to the carton adjusted through an integrated HMI.

7.9.7 Setting the height position of the tamper evident label applied on the carton (around the edge) by adjusting the labeller head by height with a threaded spindle.

7.9.8 Position indicators on each threaded spindle for quick and repeatable position adjustment regarding each product dimensions and preferred adjustments.

7.9.9 Unwinding unit with extra traction mechanism for unwinding rolls of labels.

7.9.10 Labelling with transparent or printed labels - photo sensor for transparent materials.

7.9.11 Labelling head capacity up to 25,000 labels per hour (depending on the speed of carton transportation and labels length).

Tamper evident labels presence verification:

7.9.12 Tamper evident label is attached to the lateral side of the folded carton in a way that half of it is attached to the lateral side of the carton and another half is unattached (in process of presence verification).

7.9.13 Photo sensor detects presence of the unattached half of tamper evident label.

7.9.14 Carton without tamper evident label is tracked and ejected.

Assembly for fold down and smooth tamper evident labels over the edge:

7.9.15 Unattached half of the tamper evident label is folded with a specially designed guide.

7.9.16 Tamper evident label is smooth over with a special roller.

7.9.17 Precise assemblies for folding guidance adjusting and positioning.

7.9.18 Height adjustment based on the height of the carton for each side separately adjusted.

7.9.19 Position indicators on each threaded spindle for quick and repeatable position adjustment.

Guidance for tamper evident:

7.9.20 Guidance shall to enable synchronisation and precise tamper evident applying

Labelling head stand, 2 pcs:

- 7.9.21 Positioning the labelling head regarding the folded carton dimensions and desired position of applied tamper evident label.
- 7.9.22 Accurate linear guides and threaded spindle for adjusting labelling head height regarding the carton height and desired tamper evident label position.

Tamper evidence software:

- 7.9.23 Software that runs in a separate window in HMI and enables managing tamper evident labels applying – both tamper evident applicators, tamper evident labels presence verification, non-verified cartons ejection, data logging and statistics.
- 7.9.24 All components of device are connected to the local network, which enables the optional connection with remote access in case of troubleshooting, control, configuration and management of complete device and all the components.
- 7.9.25 Centralized monitoring of tamper evident labels applying over a HMI (operating mode, running out / out of labels, integrated display of all the warnings and errors, drives error, etc.) and based on all these data relevant signalization and reports.
- 7.9.26 IT support for the tamper evident verification.
- 7.9.27 Statistics on folded carton tamper evident labels applying: the number of all/good/ejected.
- 7.9.28 Service mode for testing and adjustment of the tamper evident labels applying system.

7.10 Line manager serialization module

Communication/interface between Line Manager System and Plant Manager System:

Line manager system can be implemented as machine extension, or as a part of Plant Management system for serialization.

- 7.10.1 Communication with database.
- 7.10.2 Plant Manager System activates work order; all generated unique serial numbers are transferred to local server on the P&V or alternatively managed by Line manager integrated as part of Plant Manager System for serialization.
- 7.10.3 Automated generation of work orders list is implemented for user to manually choose specific work order.
- 7.10.4 All missing data can be manually entered on machine at batch start.
- 7.10.5 Data on used unique serial numbers status is sent back to Plant Manager System for serialization during operation in both online mode and after the execution of work order (data is transferred based on set period of time or based on actual production quantity).
- 7.10.6 After operator on P&V closes work order information is sent to Plant manager and status of all previously unreturned unique serial numbers (used, non-verified rejected to ejection bin, physical excluded verified cartons, in-process control, unused) together with »Work order closed« status and other relevant data is sent to EPCIS database.
- 7.10.7 Batch report is created at end of production and sent to Plant Manager System for serialization.
- 7.10.8 Time and date synchronization with local site's time server through integration with plant manager system.
- 7.10.9 Continuous operation in case of connection loss to Plant Manager System for serialization with immediate synchronization on connection reestablishment.

P&V integrated user interface extension:

- 7.10.10. Additional Serialization window in integrated user interface of P&V machine with additional functions for serialization process management.
- 7.10.11 Displaying of work order and managing the status of the work order.
- 7.10.12 Batch start available only when all cooperating systems are ready for production.
- 7.10.13 Calculating work order statistics.
- 7.10.14 Batch controls allow different batch statuses on machine.
- 7.10.15 System automatically resumes work after reboot in case of power loss while operating in batch mode.
- 7.10.16 Test marking in the phase of packing line set up.
- 7.10.17 Displaying of all relevant information needed for carton marking.
- 7.10.18 Additional alarms and displays for errors monitoring.
- 7.10.19 Configuration of the rights for individual operations based on different user's levels.
- 7.10.20 Support for multilingualism.
- 7.10.21 Local review and export options for audit trail and batch reports stored on Plant Manager System for serialization.
- 7.10.22 Creation and modification of recipes and print templates stored on Plant Manager System for serialization.
- 7.10.23 Local review and export options for recipes stored on Plant Manager System.

P&V functional serialization extensions:

- 7.10.24 Extending the communication with the printer with support for sending assigned unique serial numbers intended for printing.
- 7.10.25 Extending the communication with a verification system for sending assigned unique serial numbers as reference for the verification content.
- 7.10.26 Printer operations and verification system synchronization control.
- 7.10.27 Logging changes of the serial numbers status for later sending data back to Plant Manager System for serialization.
- 7.10.28 Audit Trail extensions for new operations.
- 7.10.29 Wide support for different countries regulatory requirements.

Subsequent manual operating with verified cartons:

- 7.10.30 Software for manual managing status changes of verified cartons in further processing of cartons in the packaging line.
- 7.10.31 Status changing due to in-process control execution.
- 7.10.32 Status changing due to withdrawing cartons from stretch banding machine, withdrawing on case packer, rejection of non-verified code of case transport label, withdrawing on palletizing unit.
- 7.10.33 Code reading on withdrawn cartons with wireless handheld scanner.

7.11 Control system for P&V

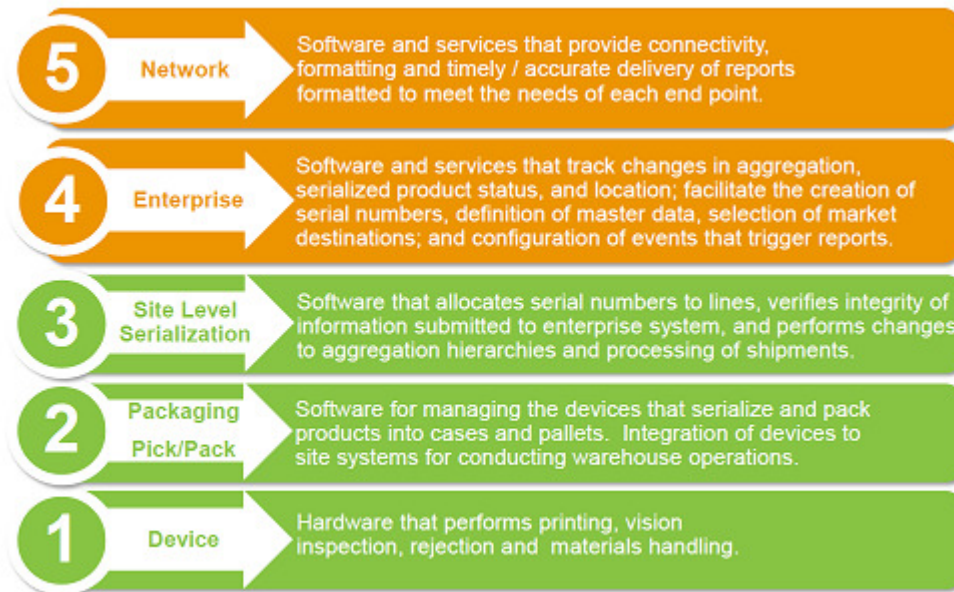
- 7.11.1 The machine shall have a fully programmable control system with a possibility to define values and programs for process and maintenance, including warning and alert limits.

- 7.11.2 The control system shall be in compliance with the current GAMP.
- 7.11.3 The machine control system shall stop the machine automatically in case of electrical power supply failure, loss of air supply or other major utility and shall require the operator intervention to re-start.
- 7.11.4 UPS for the Control System shall be provided.
- 7.11.5 Any fault or deviation from the set values/limits shall lead to an alarm signal.
- 7.11.6 The machine shall comply with the current European safety legislation, and shall bear the CE Mark.
- 7.11.7 All guards, covers, lids, doors, or any other openings shall prevent access to moving parts when in motion.
- 7.11.8 P&V shall have at least:
- Doors with safety switches,
 - All necessary sensors for the machine operation,
 - Photo sensor for print triggering,
 - Carton tracking along the whole machine,
 - Ejection control based on every single verification system,
 - Ejection execution control,
 - Pressure control of compressed air for ejection,
 - All necessary safety switches,
 - Emergency stop switch,
 - Photo sensor for tamper evident labels presence verification.

8. BASIC REQUIREMENTS FOR PLANT MANAGER SYSTEM FOR SERIALIZATION

8.1 General System Requirements

System shall be provided as Cloud principles based solution, and should be Integrated Enterprise level solution, independent from HW/SW platforms and environments. System has to be already developed solution, and SW vendor providing a solution should be evaluated by leading SW analysts like IDC and/or Gartner. Software vendor providing solution should support and be a part of Open Foundation – Open Supply Chain community (Open SCS) prior to date of publishing this URS, and should commit to align solution according Open SCS standard once it will become available. In order to evidence this, supplier should sign written auditable confirmation.



Serialization Framework

System has to support all functions L2-L5 no matter if Galenika will use system on all levels.

Solution should support:

Multi-instance configurations, where entire middleware and solution components are separated and isolated inside Virtually or Physically separated environments:

- 8.1.1 Multitenant solution, where within one instance solution has ability to create separate logical tenants, logically isolated from other tenants. Tenants inside one instance will share configuration and process information, as well as software version levels, while configuration of each tenant is independent from another tenant inside same instance, with possibility to easily configure tenants based on specific tenant needs. Tenants may act as separate serialization solution, but also should be provided to CMOs, 3PLs, Distributors and wholesalers, or should represent one floor, site or another organizational unit.
- 8.1.2 System shall support creation of theoretically unlimited number of tenants within one instance, where each tenant has to have possibility to be configured independently of other tenants for any other then configuration information and software version.
- 8.1.3 Serialization system shall support selection of different infrastructure and middleware components, based on Enterprise architecture choices.
- 8.1.4 Serialization system shall enable all functions as Web API interfaces, accessible either as XML or JSON while supporting easy mapping between different XML structures using Integration and Transformation layer
- 8.1.5 System shall have ability to work in clustered environment, and shall not have single point of failure regarding software architecture.
- 8.1.6 System shall enable easy to configure Disaster recovery capability.
- 8.1.7 System shall have ability to support Multilanguage environments based on all labels used within solution, where has to have possibility to define its own, multiple vocabulary of words to be used, in tabular form. Once assigned to system, each user of the system has to have possibility to select language or vocabulary based on personal preferences.
- 8.1.8 System shall be highly secured and permit access to manual change of data only under strict and defined conditions.

- 8.1.9 Reporting from Plant Manager System for serialization to EU Hub shall base on EPCIS standard or standard that EU hub demands.
- 8.1.10 For reporting to other regulatory authorities (e.g. Russia, EU ...) it shall be possible to prepare user defined reports and data export in various formats (TXT, CSV, XML...).

Infrastructure Requirements

- 8.1.11 System shall have well defined authentication engine, where authentication source could be from internal database/repository, and from external, like Organization LDAP. Each tenant should have possibility to be integrated with different LDAP, and one organization may have multiple authorization LDAPs. Rules for password creation shall have possibility to be defined regarding length and structure, have password expiration period and possibility to retrieve and change password using alternate channel, e.g. email.
- 8.1.12 Authorization – roles shall be assigned to activities users are allowed to perform. Activities should describe action role is allowed to undertake like add/edit/delete. Activities should enable to customize what users are allowed to access. Roles should have hierarchy, so that certain roles could be logically grouped and assigned to users. Authorization should be performed on service level.
- 8.1.13 Audit Trail – each action within system shall be logged, including viewing, modifying or creation of data. Audit trail should consist of answers to questions what, where, why, how, when and should be structured as a log, with links to more descriptive information. Log should be searchable. If change will occur, data before the database changed should be translated into XML structure on table level (reflecting to affected table) and such structure should be stored in database, accessible from log record.
- 8.1.14 Quality approval paths – system shall allow creation of approval path, describing quality assurance processes
- 8.1.15 Process Management – system shall have possibility to graphically model processes. This has to orchestrate system functionalities, in a way that web API services should be exposed to process server, and interaction has to be established using graphical means. Process could be defined in a way to interact with human and machine users, raise alarms, and trigger additional processes based on logical analysis of input/output parameters.

8.2 Unique serialization number generation

- 8.2.1 System shall allow creation of unlimited number of serial generation templates, using sequential and randomized algorithms. For randomization of serial numbers at least Mersenne Twister algorithm shall be implemented. For sequential number generation, system shall use parameterization, where starting number and step should be configurable.
- 8.2.2 System shall verify against database that serial numbers are unique, if they are randomly defined.
- 8.2.3 System shall allow easy adoption of other generation algorithms.
- 8.2.4 Randomized numbers should consist of custom definable characters, including numbers, letters and special characters based on Unicode character set. Definition of characters that will be used in generation of serial numbers should be easily template in a way that Galenika have possibility to define custom alphabets, consisting of characters.
- 8.2.5 System shall allow creation of generation templates, so that structure, length and alphabets could be assigned to template, and each template should have unlimited numbers of sequences, e.g. fixed part of certain length, followed by randomized part constituted from alphabet sequence,

- followed by other sequences.
- 8.2.6 Serial number templates shall have possibility to be generated for stock, where minimal and maximum levels of the stock should be defined by the Galenika.
 - 8.2.7 Serial number templates shall have validity period, and Responsible user shall have alarm if expiration date is approaching for certain template.
 - 8.2.8 System shall have possibility to remove used serial numbers from system and reuse them, and period for such action should be defined individually for each template.
 - 8.2.9 For each tenant of the system, independent random number generators could be used, however if certain tenant is to use generation templates from its parents, then usage of Serial number generation inside tenant should be disabled.
 - 8.2.10 System shall enable easy insight into generated number stock levels and work orders.
 - 8.2.11 Work orders for generation of certain number of serial numbers shall have possibility to be started automatically using predefined scheduled tasks, or manually.
 - 8.2.12 System shall enable exchange of the serial numbers between different instances and tenants of the system, but also with external parties. System has to:
 - Allow manual import and export of serialized number in different formats, like text, excel and xml,
 - Allow automated export of the serial numbers to external parties, using EPCIS interfacing. External parties could be defined as: CMOs – requesting serial numbers from Plant Manager System for serialization to be printed by external manufacturer of the products, MAHs – delivering serial numbers to be used at internal printing facilities by Client, Government agencies – delivering serial numbers from external sources and Other Serialization systems.
 - 8.2.13 System shall allow configuration of subjects for exchange of serial number. Each subject has to be described with necessary attributes, like name, address, etc, and those attributes should be grouped into vocabularies. Subject should have possibility to automatically expire (access forbidden).
 - 8.2.14 Attributes shall have verification rules.
 - 8.2.15 Subjects shall be assigned a role in order to access the data.
 - 8.2.16 During automated data exchange, the system shall allow transformation of data between different formats, like EDI or XML.
 - 8.2.17 System shall support creation of market templates which will be used to distinguish requirements for serial numbers, label type, required information, code, etc between different regulations. Those Market templates shall be configurable to adopt most demanding Galenika needs
 - 8.2.18 Unique serialization numbers shall be generated centrally for Galenika. Serialization numbers shall be generated in advance and not for particular shop floor order.
 - 8.2.19 It shall be possible to get external serialization numbers where particular set of serialization number can be assigned to particular material ID or particular batch No.
 - 8.2.20 Algorithm shall assure uniqueness of serialization numbers throughout the life cycle of the system (at least 50 years).

8.3 Product Catalogue

- 8.3.1 System shall support creation of unlimited number of product catalogues, each containing hierarchy of products up to unlimited level.
- 8.3.2 Each product shall be described with custom definable attributes, where each attribute can have validation rule, like length, type, etc.
- 8.3.3 Attributes shall have possibility to be grouped into vocabularies. One attribute may belong to one or many vocabularies, and one product can be assigned to as many vocabularies as needed. Attribute may have default value pre-set.

- 8.3.4 System shall support GDSN vocabulary and GS1 Business vocabulary by default.
- 8.3.5 System shall allow creation of aggregation vocabularies that can describe how individual items (SKUs) are packaged, bundled and aggregated. One product may have many aggregation possibilities.
- 8.3.6 Product catalogue shall allow easy integration from and to external sources, like GDSN network, SAP, etc. using transformation and integration infrastructural layer.
- 8.3.7 Change, creation or removal of products, attributes and hierarchies shall have approval paths enabled and shall allow digital signature when change is requested.
- 8.3.8 Product catalogue shall allow different views or perspectives, but at minimum creation of three lists. Product views shall be related to Markets, so that each product may be described based on market where it is marketed.
- 8.3.9 Products, vocabularies and attributes may have validity duration, and user shall be alarmed in case certain attribute, vocabulary or product is to expire.
- 8.3.10 System shall allow each product to be accompanied by product documentation, either attached manually or accessible from external systems.
- 8.3.11 System shall allow reports, and at least reports of issued serial numbers per product.

8.4 Manufacturing Control

Manufacturing control types of requests for manual, semi-automated or automated actions to be executed in order to complete different requests of serialization regulatory requirements. Manufacturing control consists of information and attached process for execution.

Manufacturing control types should be of the following types: Print Order, Verify printed order, Print and Verify order, Aggregate order, Disaggregate order, Repackaging order, Transfer order.

- 8.4.1 System shall be process oriented based on specified Manufacturing control tasks, which means that any request for execution generated by the system shall be in the form of Manufacturing control.
- 8.4.2 Manufacturing control may be created manually or automatically. In case of automatically Manufacturing control creation, system shall verify information, and raise alarms if human interaction is required.
- 8.4.3 Manufacturing control process flow shall have possibility to be defined using internal process server.
- 8.4.4 System shall allow management of manufacturing control, like editing, cancelling, modifying controls, listing and insight into controls up to individual item level.
- 8.4.5 Each Manufacturing control, when applicable (print and verify, aggregation) shall have possibility to define more than one device for execution, so that Manufacturing control can be executed simultaneously on many devices, e.g. Manufacturing control for printing the labels can be sent to two or more printers for execution.
- 8.4.6 System shall allow transfer of the Manufacturing control to external equipment, like Print and Verify equipment, aggregation devices, etc. using ISA-95 interfacing.
- 8.4.7 Manufacturing control shall describe exactly which manufacturing action will be performed, and shall include all relevant data, such as Product, Market identifier, Quantity, Aggregation details, etc.
- 8.4.8 Manufacturing control shall have interactive, online dashboard so that actual execution could be monitored, accurate to the level set by equipment itself.
- 8.4.9 Manufacturing control shall have different views that allow easy insight into historical and current Manufacturing control.
- 8.4.10 System shall support Scheduling of Manufacturing control and forwarding orders between

similar types of equipment (e.g. from one printer device to another).

- 8.4.11 System shall allow repackaging of aggregated products in forms of special type of Manufacturing control.
- 8.4.12 Information about Manufacturing control shall be stored in EPCIS database, after the execution of the work order.
- 8.4.13 Manufacturing control shall have possibility to be viewed in details, up to individual item level.
- 8.4.14 Label attached to individual item or package should have possibility to be previewed.
- 8.4.15 Manufacturing control shall be exportable in different formats, but at minimum to textual, PDF and XML data files.
- 8.4.16 Aggregation, disaggregation and repackaging shall be of such kind that bundles are allowed to be created from same and different types of products. Such bundling actions shall be graphically represented using diagrams and, if applicable, shall also represent movements between Subjects.
- 8.4.17 Transfer orders shall create internal movement of labelled products throughout supply chain.

8.5 Organization management

- 8.5.1 System has to have possibility to model organizational structure in such a manner that it recognizes attached equipment, with online integration to equipment functions, organizational units, like Floors, Sites, Companies, Warehouses in a way that it is possible easily to assign new parts of organization.
- 8.5.2 Organizational parts should belong to Organizational Vocabulary, which will be used to describe different parts of organization
- 8.5.3 System has to have GUI with drag and drop feature to easily model organization components. Each component should be accessible from within the System. Organization components running on same instance, but different tenants should be visible and accessible by the System in a manner that the main operations, such as Work orders, Logistics, etc., can be performed.

8.6 Managing Exchange of Data

Under the term of Serialized items data all information gathered in actions over printed and verified labels is considered. This information in general should give answers to who, what, where, why, how, when questions.

Such data should be exchanged with:

- Other System instances and tenants,
- National Agencies and Repositories,
- External subjects like 3PLs, Distributors, Warehouses, MAHs, CMOs and possible other parties involved in serialization process,
- Internal subjects, like internal warehouses, equipment for P&V, aggregations and disaggregation's, handy scanners and printers, different internal web services, like those exposed from ERP, DMS, CRM, MES.

All actions on data containing serialized items, other than communication with internal IT systems and equipment, should be performed using EPCIS standard.

- 8.6.1 System shall have flexible integration layer that can easily perform different transformation between the data, but at least transformation between XML structures, from and to EDI.
- 8.6.2 Transformation layer shall be integrated with process layer which will control flow of the messages and routing messages between different components.
- 8.6.3 Transformation of the XML structures should be performed with Graphical interface that will allow mapping of the XML fields, creating XSLT stylesheet.

- 8.6.4 For communication with equipment used for serialization (P&V, aggregation, disaggregation) ISA-95 interfaces should be supported or alternatively interface prescribed by OPEN SCS standardization authority. ISA-95 interface should also be connected to transformation layer or should be a part of transformation layer.
- 8.6.5 System shall allow creation of internal (organizational) and external (supply chain) subjects, where subject description data should be definable with vocabulary. Each subject should have also validity date, and subjects are not allowed to access information if validity will expire.
- 8.6.6 Exchange of logistic data shall be performed using EPCIS. In case subject is not registered to database, but tries to report movement of serialized items, Subject should be created. Minimal subject information could vary based on specific market template.
- 8.6.7 Mapping of the data exchange sources, in case of internal data exchange should be performed in such a way that it is possible to configure organization components and assign of allow imports and exports of serialization data.
- 8.6.8 System shall have alarms and notifications using GUI, when human interaction is required, e.g. in order to transfer shipments or import subject to EPCIS.
- 8.6.9 System shall allow export and import of data from internal and external sources in pdf, xml and excel form, so that it is possible to manually perform data exchange.
- 8.6.10 When using data exchange for transfer of products within supply chain, system shall support movements based on predefined or random routes. If certain serialized product is moving on specified predefined route, system should notify for any inconsistency with planned route.
- 8.6.11 System shall provide visual representation for all movements preferably using graphical map, like those from Google maps.
- 8.6.12 System shall support possibility to monitor stock levels of external parties and report on stock levels, with possibility to set minimal (critical) stock level values.
- 8.6.13 System shall support recall logistics, and should graphically present recall path, which should be reverse path of those used for distributing the serialized item.
- 8.6.14 System shall support recall reporting to national agencies automatically, on lot and item level.
- 8.6.15 System shall enable manual status changes before data are sent to central EU Hub (e.g. samples, damaged products, etc). Each status change of particular record should be traced with who/when/why traceability (audit trail).

8.7 Labelling Definition

To enable easy creation of labels, specific tool shall be developed that will integrate different requirements in templates. Those templates shall have descriptive name, and shall consist of geographical identification (area where to be used), visual representation of data carrier (1D, 2D code, NFC, RFID, etc) and set of attributes required by specific regulation where the template will be applied.

- 8.7.1. System shall allow creation of label templates. Each template consists of type of carrier used for coding data, assigned vocabulary containing attributes, where certain attributes will be collected from other solution components or external systems (e.g. Production date could be available after the production is completed, and Lot/Batch numbers are available from manufacturing control).
- 8.7.2. System shall allow creation of unlimited number of labelling standards. At least following has to be predefined: GS1, IFA PPN, EHBCC.
- 8.7.3. System shall allow linking of label to proper serialization number template, so that production order can collect from serial numbers warehouse properly generated templates
- 8.7.4. Label templates shall be assigned to manufacturing control and should define rules for their behaviour, label that will be printed during the process (depending on manufacturing control order type) and shall in combination with manufacturing type contain all data required to

successfully either serialize or bundle (aggregate) products.

9. DATA, RECORDS AND SIGNATURES IN THE SYSTEM

All data, records and signatures shall be compliant with CFR 21 Part 11/GMP EU Anex11 regulations.

9.1 Data

- 9.1.1 Data definition with list of critical data and data limits: required data are described in chapter 2, 8.1, 8.2, 8.3, but the system shall allow easy templating using vocabularies and dictionaries.
- 9.1.2 Database size requirements: check chapter 10. Limitations of the system -> Capacity request below.
- 9.1.3 Data retrieval response time (actual and archive data): systems shall enable normal execution of production without delays. Retrieval of archive data can be slower.
- 9.1.4 Transfer of initial data from existing systems: there is no transfer of initial data from other existing or legacy systems.
- 9.1.5 Backup/Restore/Archiving requirements': Backup will be done on database level. Systems shall have option to archive data to archive database after data retention period expires. This is required for Plant Manager System for serialization. Serialization System shall mark data for deletion after successful transfer to Plant Manager System for serialization.

9.2 Records (Documents)

- 9.2.1 After production is finished, final electronic record links manufacturing order with all produced packages with unique serial numbers; together with produced serial numbers also samples and destroyed numbers shall be recorded.
- 9.2.2 These data shall be sent to Plant Manager System for serialization and after batch is released, all required data shall be sent to EU Hub (or other national agency for other markets, who require serialization).

9.3 Signatures

Galenika has decided to adopt electronic data handling system in accordance to GMP EU Annex 11 (21CFR Part 11). By designing of computerized system at least following guidelines shall be followed:

- 9.3.1 Electronic signature: All GMP and safety critical operations (manual changes of statuses) must be protected by electronic signature (username and password).

9.4 Audit trail

- 9.4.1 Audit trail records are created for all manual changes of statuses and record entry or changes.
- 9.4.2 Automatically generated or exchanged records must be equipped with time stamp Audit trail records must be created for:
 - Events (Changes of all GxP parameters in a system, User actions),
 - Alarms (critical and noncritical).
- 9.4.3 Audit trail record shall contain at least the following information:
 - When the change or action occur,
 - Change or action description,
 - Old and new value (for example: from 10 to 20 or from status Created to Reviewed),
 - Who made a change or action.

- 9.4.4 Audit trail shall be stored/copied on central servers and not locally.
- 9.4.5 User should be able to filter audit trail data upon different criteria such as criticality, type, time, etc. and to print them out as report. System shall be designed to record only relevant events. The criteria what is relevant or not shall be discussed with Galenika.

10. INTERFACES

10.1 User interface with description of roles:

- Operator, Technician: data overview, data entry for samples and destroyed numbers,
- Technologist: additional possibility of status change,
- Administrator: configuration of the system.

10.2 Interface to the other Galenika systems with criticality assessment:

- MRPII Unisys BAMSC,
- BMS,
- T&D,
- WMS,
- Optionally interface for manufacturing order is done from ERP -> Serialization System (GXP critical, provided by vendor and partially provided by Galenika).
Interface can be implemented with different interface technologies: BAPI, Web Service call or IDoc interface.

10.3 Interface between Plant Manager System for serialization and Repository, between Plant Manager System for serialization and Generator and between Plant Manager System for serialization and P&V (all GXP critical and provided by vendor):

- Interface technology is not prescribed, it can be implemented on database level (interface tables, views etc.) or with standard interface technologies (Web Service calls, IDocs, XMLs etc.).

10.4 Interface to equipment (sensors, activators):

Interface between P&V module and the rest of the packaging line:

10.4.1 P&V system shall be able to communicate up- and downstream of the packaging line.

10.4.2 Normally this is achieved by using potential free contacts with the following functionalities:

- P&V module blocked or in alarm stop the upstream machine.
- Downstream machine stopped or in alarm stop the P&V module.

11. ENVIRONMENT

11.1 Description and request to environment, where system will be used: production equipment must follow production environment standards.

11.2 Requirements for development, test and production environment: System has to have all three environments. Development system can be installed on vendor infrastructure at vendor site. Test and production environment have to be installed on Galenika infrastructure.

12. LIMITATIONS OF THE SYSTEM

- 12.1 Compatibility to existing system (HW, SW, network): System should run on Galenika standard IT infrastructure (Microsoft Windows Server 2008 R2, Microsoft SQL 2008, Microsoft Windows XP or Windows 7, Microsoft Forefront Threat Management Gateway 2010).
- 12.2 Capacity request for whole system (OS, application, data etc.):
 - 12.2.1 Application size requirement: ~100 GB for each application server (together with OS).
 - 12.2.2 Database requirement: total required quantity will be known after detailed analysis of SW solution and DB architecture. Approximate estimate for repository is 1-2 TB/year (at 250 Mio pieces produced quantity), for all other databases (generator, LS, P&V system) estimated size is 10-20 GB/year.
- 12.3 Speed access to the system: system should perform normal operations without delays.
- 12.4 Requirements for the operation of the system (24/7):
 - 12.4.1 Plant Manager System for serialization and P&V system has to be available during production hours of all connected packaging lines and must be also available 24/7 regime. Maintenance is only possible when connected production lines do not operate.
 - 12.4.2 Plant Manager System for serialization and serial number generator must be available in 99,5% of 24/7 regime.
- 12.5 Required actions when error appears: if error appears, system should trigger alarm and alert user. Error should be also recorded in error log.
- 12.6 Estimated number of users of the system: Estimated number of users is ~100-200.

13. INFRASTRUCTURE

- 13.1 Servers: applications should have server-client architecture, if possible client user interface should use HTML 5.
- 13.2 PCs: Use of standard Galenika PC equipment (PC with Windows XP, Windows 7).
- 13.3 PLCs: Siemens S7.
- 13.4 Printers: local and network printers must be supported.
- 13.5 Use of RF terminals / bar code readers: manual operations recording changes of serial numbers (sampling, write-off, etc.) must support use of RF terminals or bar code readers.
- 13.6 Network: Software must run in Galenika LAN network.

14. LIFE CYCLE

- 14.1 Development
 - 14.1.1 Minimum standards –predicate rules which has to be followed by supplier (CFR 21 Part 11, GMP EU Anex11, GAMP 5, Galenika’s rules - SOPs and VAPs).
 - 14.1.2 Procedure for project management and quality: will be defined by VAP – Validation Protocol.
- 14.2 Testing
 - 14.2.1 Special test requirements: none.
 - 14.2.2 Required test data: will be retrieved from external test system or entered manually.
 - 14.2.3 Simulations: simulations can be done in non-operating mode with software simulation or in operation mode with actual production line with test materials.
 - 14.2.4 In second case, all test materials have to be clearly marked and separated from actual production materials.

15. APPLICATION SECURITY REQUIREMENTS

15.1 Application is available from:

15.1.1 Internal network only: Encrypted authentication (username, password) required (Kerberos, LDAP, Certificate, https, etc.).

15.1.2 Internet: All traffic encryption required (https, VPN, SSH, Secure FTP, etc.).

15.2 Application has to be designed for Galenika's standard platforms (Microsoft Client and Server OS).

15.3 Application client software must be able to operate without requiring the user to have local administrator level rights.

15.4 Authentication

15.4.1 Username and password (not default one) is min. requirement for accessing the application.

15.4.2 Integration with Active Directory.

15.4.3 Application must force new users to change their password upon first login.

15.4.4 Password policy (GxP critical applications). Application must force password expiration time and prevent users' from reusing a password.

15.4.5 Application manages a session for the users (GxP critical applications). User session must be suspended "timed out" after a specified time.

15.5 Authorization

15.5.1 The application must support several authorization roles (Administrator role and user role are mandatory).

15.5.2 User Authorization can be changed only by administrator.

15.5.3 If application use user profile data to make authorization decision, the data should be stored local in the application (not in some shared repository).

15.6 Password management

15.6.1 Users must be able to change their own password.

15.6.2 Password policy (GxP critical applications). It is mandatory that password policies can be enforced with complexity such as minimum length, numbers and alphabet requirements.

15.6.3 Application must be able to automatically lock a user's account after a predetermined number of consecutive unsuccessful logon attempts.

15.7 Auditing

15.7.1 Authentication success and failure attempts auditing (GxP critical applications). Authentication success and failure attempts must be audited.

15.7.2 Authorization success and failure attempts auditing (GxP critical applications). Authorization success and failure attempts must be audited.

15.7.3 System configuration changes should be audited (GxP critical applications). Application must support auditing of system configuration changes.

15.7.4 Reporting capabilities on audit logs.

16. WARRANTY PERIOD AND MAINTENANCE

16.1 The warranty period shall be 24 months or 1,500,000 serialized folding cartons (items). The warranty period shall commence as of the date the equipment is handed over and the Project Completion Report signed by both parties.

16.2 Bidder shall ensure the on site support during the serialization startup period.

16.3 The bid shall include software maintenance services, with the prices in post-warranty period stated on an annual basis, for a minimum five year period.

16.4 In case of a P&V defect, a service technician should arrive on site not later than the next working day.

16.5 Telephone technical support shall be available and, in case of enabled remote access, direct on-line support shall be available as well.

17. TRANSPORT AND INSTALLATION

17.1 Bidder shall be responsible for ensuring, at its own expense, transportation, unloading and placing the machine at the location designated for installation.

17.2 Bidder shall be responsible for installation and connecting the equipment with the upstream and downstream machines. Galenika shall prepare the existing line for the installation of new equipment.

17.3 The bidder shall supply to Galenika specification of connections required for proper connection of the machine, following successful completion of the FAT.

18. DOCUMENTATION

18.1 Complete technical documentation for P&V shall be supplied (consisting of: certification, instruction manual and cleaning manual, technical data sheets, drawings and diagrams, spare parts list, hardware and software specifications, disaster recovery plan, unlocked backup copy for PLC and HMI with symbols and comments).

18.2 Complete technical documentation for Plant Manager System for serialization shall be supplied (consisting of: certification, instruction manual for user and administrator, functional and design specification, software specifications, disaster recovery plan, system installation and configuration guide with all software installation disk).

18.3 Complete qualification documentation for serialization integrated platform shall be supplied: Validation Plan, Risk Assessment, FS, IQ, OQ and PQ documents.

18.4 The full set of documents shall be submitted in the English language, in both electronic and hard copy format.

19. FAT AND SAT

19.1 Bidder shall prepare the documents for the P&V FAT performance and include in the quotation the time required for the FAT and the attendance of Galenika's representatives.

19.2 Bidder shall prepare the documents required for the SAT performance, the IQ/OQ/PQ documents and submit the protocols for Galenika's approval at least one month in advance.

19.3 Bidder shall clearly specify the number of qualified personnel and time required for the performance of SAT activities (equipment acceptance, installation and testing).

19.4 Bidder shall perform IQ, OQ and PQ.

19.5 Bidder shall perform equipment performance test, which shall include the capacity test, i.e. packaging of one product from Galenika's product range, with half-shift to full-shift test duration. The test materials will be provided by Galenika.

20. TRAINING

20.1 The bidder shall perform training of operators and maintenance staff and submit the training programme and duration information. The training shall ensure independent operation of Galenika operators and maintenance staff after the SAT completion.

21. BIDDER TECHNICAL QUALIFICATIONS

21.1 Bidder should have ability to provide service and support for the solution during and after project implementation at Galenika location in Belgrade, according to requirements stated in Article 16, which is proven by signed statement about providing continuous service including Service centre to at least 3 customers.

21.2 Bidder should provide a reference list consisting from at least three major regional companies where bidder has successful IT projects implemented

21.3 Bidder should have Quality system implemented and at least following certificates: ISO 9001, ISO 27001, ISO 20000

22. SERIALIZATION SOFTWARE BIDDER QUALIFICATION

22.1 Serialization software solution bidder should be worldwide recognized and should be included in reports by leading analytical companies (Gartner, IDC)

22.2 Serialization software bidder should be a part of Open Foundation – Open SCS prior to publishing of this document.

Напомена: Понуђач мора да испуни све захтеве дефинисане корисничком спецификацијом, Code: GALSDFPSIP1116URS-v1.

М.П

Потпис овлашћеног лица