



Safe Drug Delivery

Smart «Design – Implementation – Operation»

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III RUSSIAN
GMP-CONFERENCE

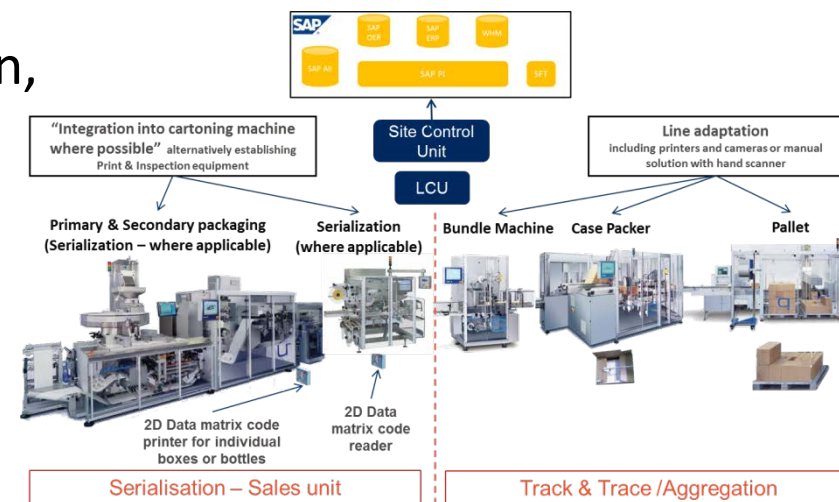
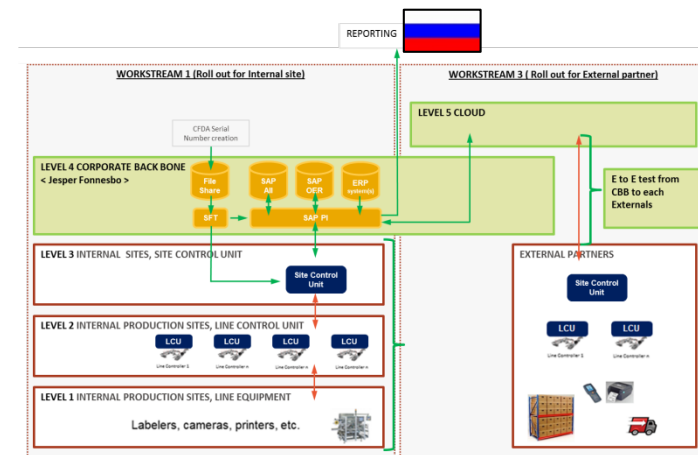
Global Patient Centric Approach

- **Global T&T Role-out** approach for E2E supply:
 - Takeda core team with 3 work-streams (sites, regulatory reporting, external partners)
 - One System Provider “Systech” for Level 2/3 (Guardian/Advisor)
 - “SAP” as EBR and “Tracelink” as a Partner
- **Takeda Yaroslavl:** 24 thousand m² production (completed Sept. 2012)
 - OSD (Oral Solid Dosage), Sterile Manufacturing & Packaging (UPI – 5 Lines)
- **Aug 1st** Takeda *Russia* held an angulation ceremony for “*Ninlaro*” full cycle high potent production in Yaroslavl incl. T&T
- Participation as a member of the **Russian T&T Pilot**
 - Start project in 2016 until December 2017: Final stage of pilot project reached by producing and selling product out of the Yaroslavl plant
 - Legislation of Russia not finalized



From the proof of concept to the real deployment

- Defined the right system architecture and Line set-up (IT – Automation – Equipment)
- Use Software as a product configurable with standard interfaces to the SAP / OEMs
- Gathered, analyzed and consolidate existing on-site situation (camera, printers, equipment etc.) and developed all necessary templates “global tool-kit” incl. ready to use training, qualification/validation package for the sites
- Established a harmonized “roll-out approach” for Serialization, Track & Trace and Tamper Evident to achieve:
 - Highest Standardization along the sites
 - Economy of scale for selected suppliers and vendor strategy
 - Minimized downtime for new installation
 - Best possible coordination and requirements with supply chain
 - Avoid repetition of effort
 - React to new products, markets and regulatory requirements



Challenges and Lessons Learned

- Harmonization and standardization driven by the global following the quality aspects (validation)
- Select the right «Track & Trace» and «OEM vendors » as partner with best available technology (contract, new releases & updates, maintenance, training)
- Force suppliers to a standardized execution with a «software product» conform with GAMP5 and all GMP/regulatory requirements
- Increase visibility across all sites E2E & enforce knowledge sharing within the industry and regulators
- Start “simple”, be patient focused before moving to a complex systems (“black box”, “Cloud” creating a "crypto code" to the GS1-DataMatrix Code”) and not able to deliver safe product in time to the market

AI	Название	Символы
01	GTIN	14 symbols
21	Serial	13 symbols
91	Crypto key	4 symbols
92	Crypto signature	88 symbols
240	National code	4 symbols (optional)
10	Batch	8 symbols optional
17	Expiry	8 symbols optional

(01) 0000012300001
(21) 0123456789123
(91) fid0
(92) 011890114008024212R82DY18HG
C02 10299JURB8817200 19 124 0320 49 118032
818782C 124009108300W489898972
pT7VW14*8*8A8T4J00v8LUB8N1CYZ0VW
R8Aq9u8m18182004

(01) 0000012300001
(21) 0123456789123
(240) 0123
(10) 00011017
(17) 211017

Minimum Module Size
of 8 dots x 8 dots

Symbol Size	Capacity
15	16
18	24
20	44
22	80
24	120
25	88

Table 2-1 Minimum Data Matrix Physical Size

