CONDOT
SYSTEMS PVT. LTD.

CSPL
TRACK & TRACE

CSPL

Can I Help You

Our GS1 Capability Matrix

Printing :
- ☑ Alphanumeric
- ☑ Barcode 1D / 2D
- ☑ Logo / Variable Logo
- ☑ Variable Data with Barcode
- ☑ Unlimited Text Line
- ☑ Application Identifier
- ☑ Unicode Printing
- ☑ Shift Code

Vision :
- ☑ OCR / BCR with ISO Grading

Compliance :
- ☑ 21 CFR PART 11 / GxP / GAMP5

Security :
- ☑ Special Security Printing for Forensic requirement

● Level of Packing

Authentication UID

01 Primary

02 Secondary

GTIN: 08912345678912
LOT: CSPL648
EXP: 22-AUG-2019
UID: 565DJNJDBUA14

GTIN: 08912345678912
LOT: CSPL648
EXP: 22-AUG-2019
UID: 565DJNJDBUA14

03 Outer Secondary — Aggregation

04 Tertiary — Aggregation

123460022
4170000000006

05 Palletisation — Aggregation

(01) 03200200034654
(17) 120101(10) qwelx2011

CSPL

About your future partner

Capability Matrix

- Variable Data Printing
- Project Management
- Infrastructure Delivery
- System Integration
- After Sales Support

We partner with Global leaders With the knowledge to Design, Implement & Support Customer needs

A **Solid foundation** lets us explore and expand without limits

We understand the demands of **both ends of work**

We're building **tomorrow** right now

Foresight lets us see opportunity but it is **character** that lets us seize it

We'll **stick** with you wherever you go

Come with us our aim is to continually increase the satisfaction of our customers

- One Stop Solution Provider
- Market Intelligence and Customer Understanding
- Accelerate growth
- Explore new areas for potential growth
- Move ahead against all hurdles
- Gather momentum by aligning resources to grow in identified businesses with high growth potential
- Execution of growth plans
- Focus on businesses with high potential
- Create growth platforms, set goals
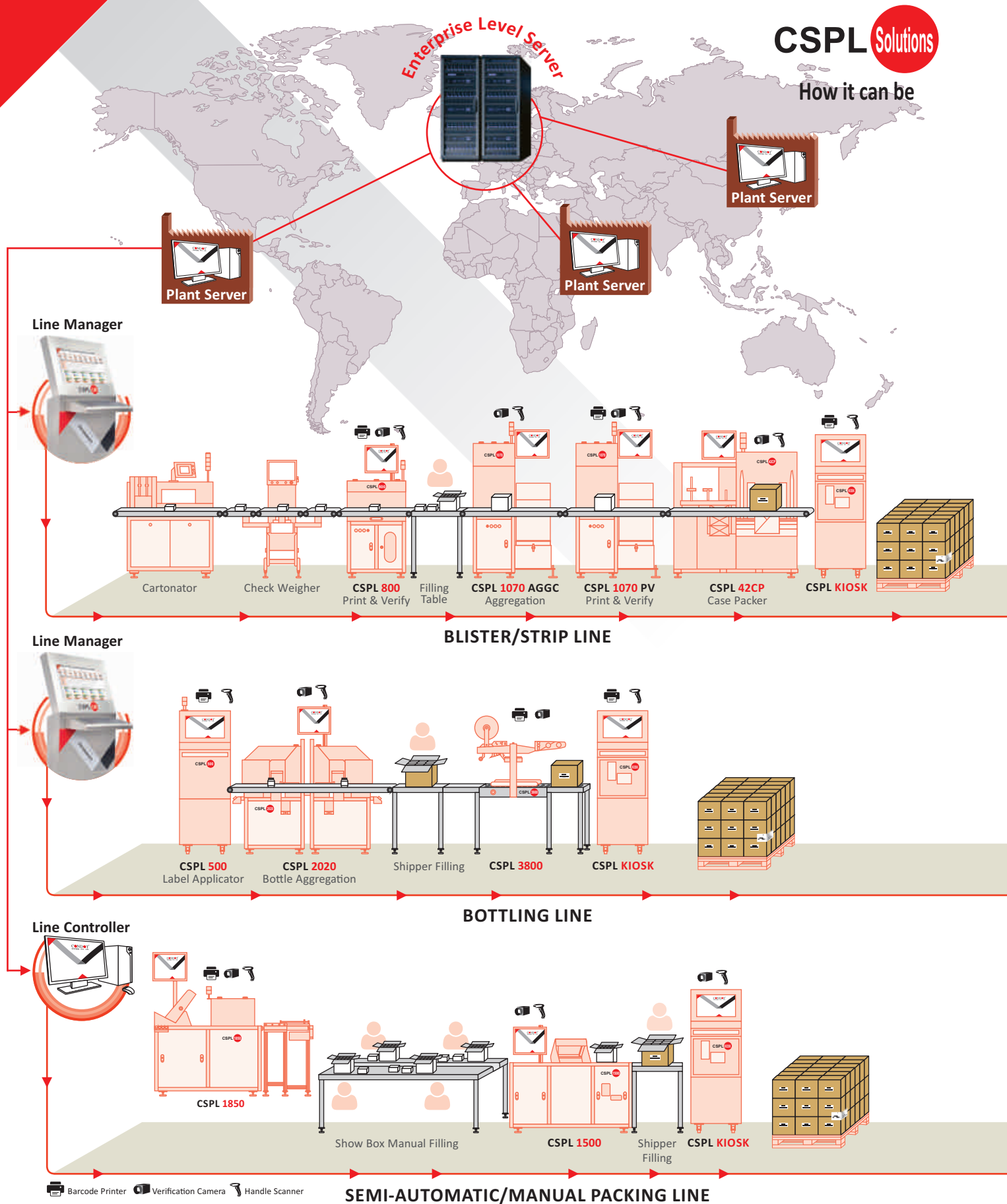- Mobilizes resources

WHY CONDOT

- Easier to Use
- Cost Effective
- More Reliable
- Fast
- Superior Quality
- Flexible
- Scalable
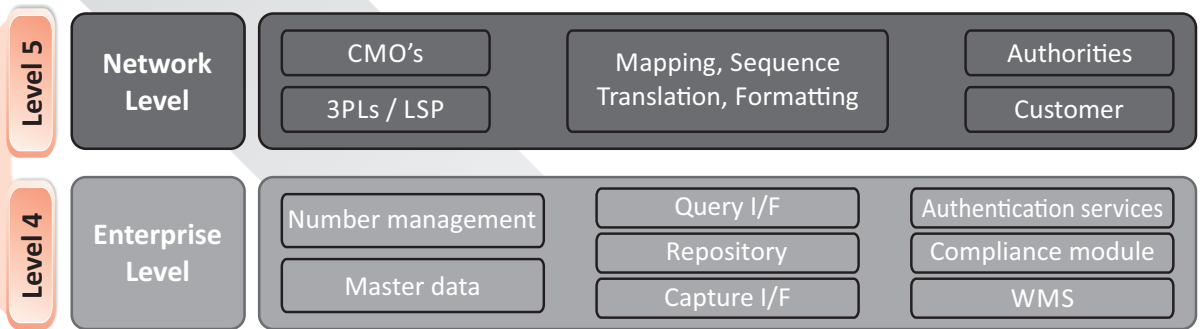- Environment Friendly
- Low Cost Ownership

OUR MAJOR FOCUS

- Brand Loyalty
- Customer Retention & Relationship
- Remove spurious products from supply chain management
- Track and Trace
- Serialization
- Authentication

CSPL Solutions

How it can be

Enterprise Level Server

Plant Server

Plant Server

Plant Server

Line Manager

| Cartonator | Check Weigher | **CSPL 800** Print & Verify | Filling Table | **CSPL 1070 AGGC** Aggregation | **CSPL 1070 PV** Print & Verify | **CSPL 42CP** Case Packer | **CSPL KIOSK** |

BLISTER/STRIP LINE

Line Manager

| **CSPL 500** Label Applicator | **CSPL 2020** Bottle Aggregation | Shipper Filling | **CSPL 3800** | **CSPL KIOSK** |

BOTTLING LINE

Line Controller

| **CSPL 1850** | Show Box Manual Filling | **CSPL 1500** | Shipper Filling | **CSPL KIOSK** |

📠 Barcode Printer   📷 Verification Camera   🔫 Handle Scanner

SEMI-AUTOMATIC/MANUAL PACKING LINE

Enterprise level solution comprises of hardware and software. Software built with Enterprise level to communicate with plant and line level. Hardware is designed to cater different production line from manual, semi-automatic and fully automatic production line for strip, blisters, injectable, vials, orals, power, dry syrups and bulk drug production lines. Hardware at every level comprises of print and verification as well as aggregation system to cater number of packing level from show box till palletization.

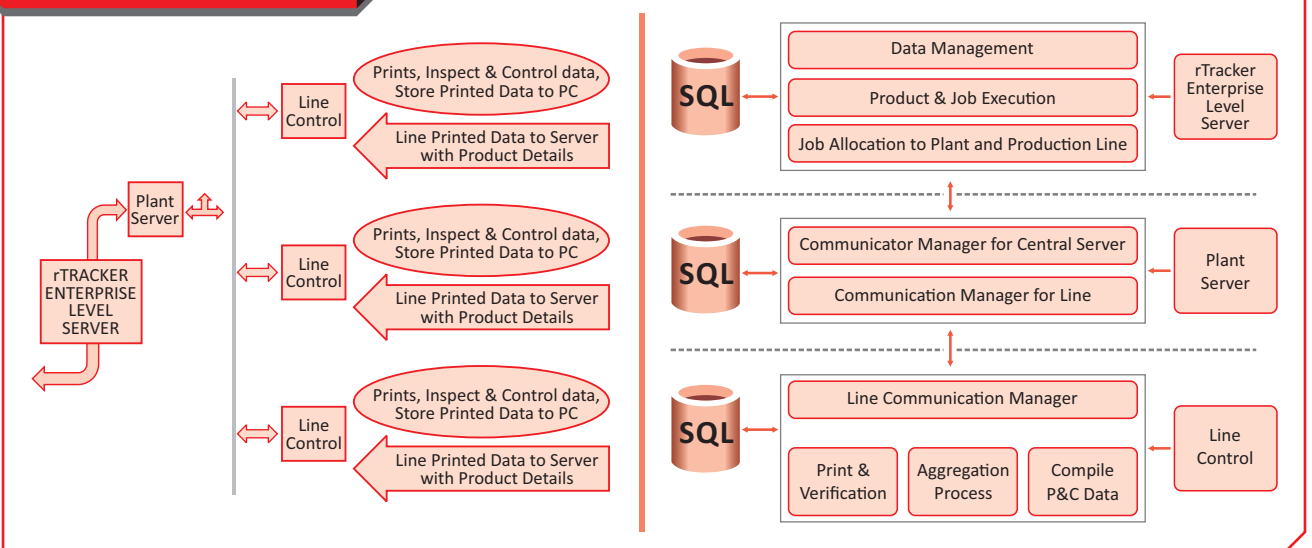# CSPL rTracker

Track & Trace Serialization Software

Track & Trace Level wise Serialization

| Level 5 | Network Level | CMO's / 3PLs / LSP | Mapping, Sequence Translation, Formatting | Authorities / Customer |

| Level 4 | Enterprise Level | Number management / Master data | Query I/F / Repository / Capture I/F | Authentication services / Compliance module / WMS |

Collaboration Layer

| Level 4 | Enterprise Level Server | Number management | Master data | EPCIS (V.1.2) XML | Report |

| Level 3 | Plant Server | |

| Level 2 | Line Control | Line Manger | Packing Line |

| Level 1 | Module | |

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SYSTEM ARCHITECTURE

- Prints, Inspect & Control data, Store Printed Data to PC
- Line Printed Data to Server with Product Details

Line Control

Plant Server

rTRACKER ENTERPRISE LEVEL SERVER

SQL — Data Management / Product & Job Execution / Job Allocation to Plant and Production Line — rTracker Enterprise Level Server

SQL — Communicator Manager for Central Server / Communication Manager for Line — Plant Server

SQL — Line Communication Manager / Print & Verification / Aggregation Process / Compile P&C Data — Line Control

rTRACKER ARCHITECTURE

Flexible, Scalable and Seamless approach for present and future-ready solution to the demand of Serialization in Pharma Industry.

Leading brands around the world have faced complex Serialization challenges in response to varied legislation. A critical part of compliance, in generation, is management, exchange and reporting of serialization data within the ecosystem of trading partners and regulatory bodies.

Before dealing with the acquisition of machinery to comply with the regulation, it is wise to think about the look of the software along with its safety, reliability, scalability and monitoring of all the processes that are enforced by the legislation throughout the world for pharmaceutical products with a unique serial number and assured traceability.

rTracker offers a full range of options to fulfil the individual requirements of product tracking. The modularity of the software architecture guarantees maximum flexibility an easy to implement and customize. Network architecture with a centralized approach allows in order to enable central management and an exchange of serialised data.

rTracker scalability can also administrate, an almost infinite UID range, even when they are produced and packed at same time in multiple lines or machines for different customers, products and countries. With rTracker, the world of serialization and track & trace is open to you, process safe and more efficient.

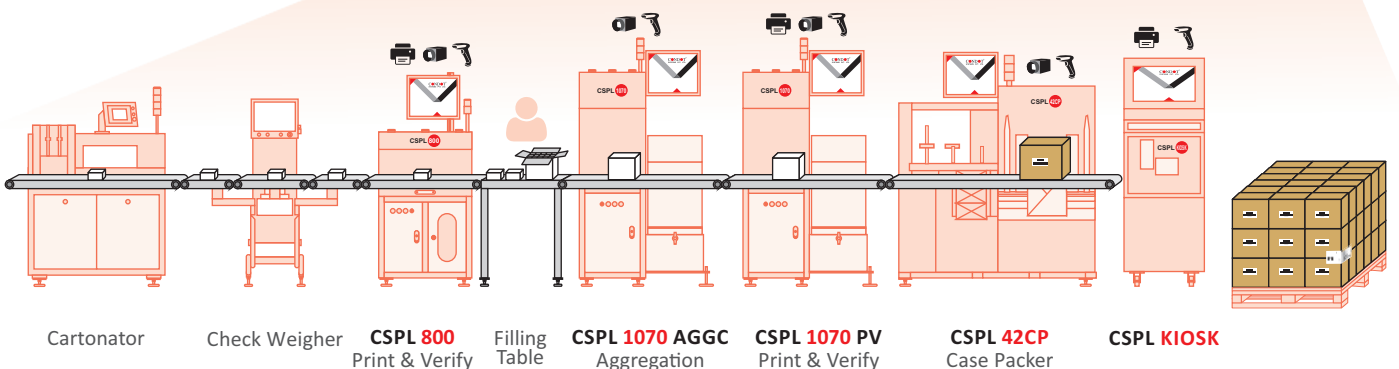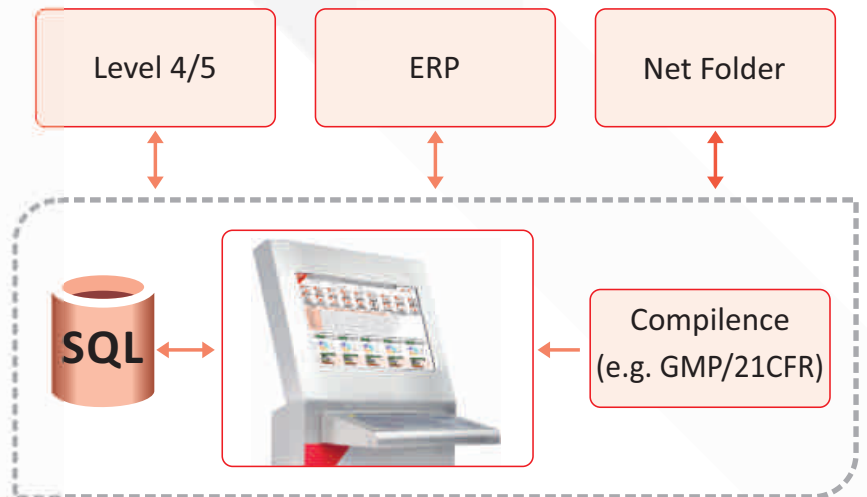rTracker modular architecture adapt to grows with your needs.

rTRacker is a One-Stop System solution for serialization and track & trace processes, which can also be used as an intelligent production management software on machine, line, plant or rTracker Enterprise Server.

It is also possible to extend the abilities of a line or a machine with additional functional software modules. The modular software architecture gives an added advantage of needless, costly and time-consuming revalidation and qualifications process.

rTracker's other salient features are available, such as, Job can be split over a number of production lines, allows controlling and administrative aggregation process in automatic or manual packaging line. The number of hierarchies can be adapted freely without the need of programming. It is also possible to manage the re-packing and quarantine samples in the warehouse.

Generation and export of audit trail and production report consists of aggregation, samples, commissioning / de-commissioning, rejection, and unused codes, along with required integration of custom-made ERP and third party, level 4 & 5 compliance solution provider.
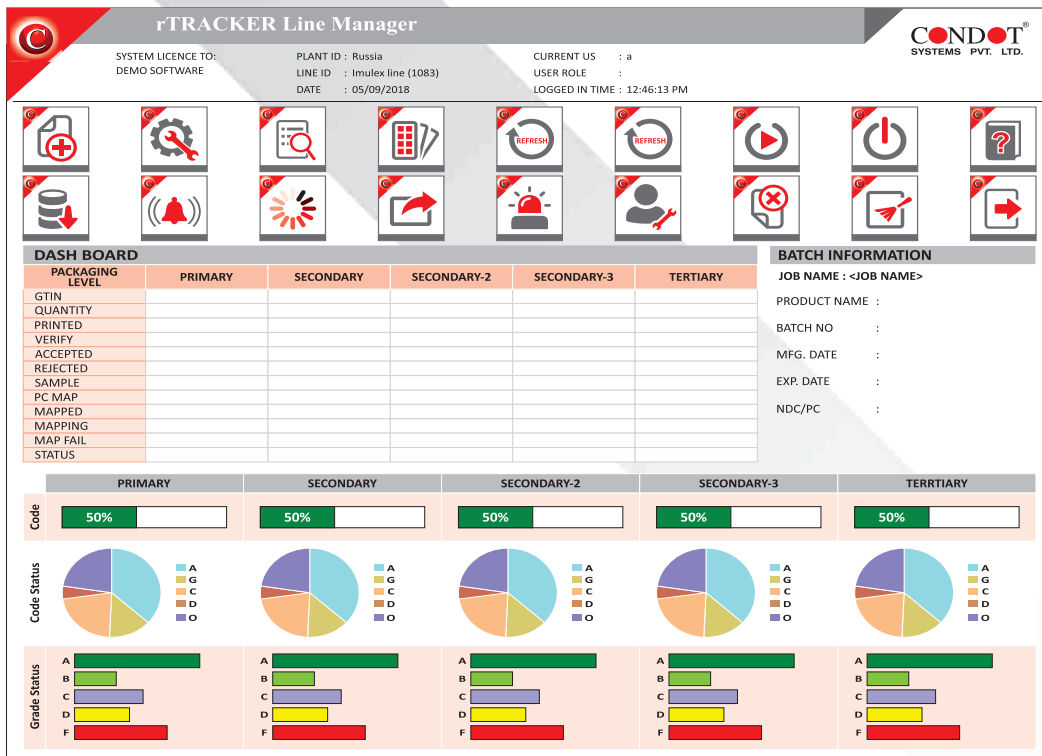
rTracker built with Standards of cGMP and required user management and data security as per 21 CFR Part 11 which is based on a predefined user group with specific rights, enhances the process safety, minimizes potential sources of error and renders it audit-proof.

CSPL LM
LINE MANAGER

Level 4/5   ERP   Net Folder

SQL

Compilence (e.g. GMP/21CFR)

| Cartonator | Check Weigher | **CSPL 800** Print & Verify | Filling Table | **CSPL 1070 AGGC** Aggregation | **CSPL 1070 PV** Print & Verify | **CSPL 42CP** Case Packer | **CSPL KIOSK** |

Flexible, Scalable and Seamless approach for present and future-ready solution to cater the demand of serialization in pharma industry.

Line manager is designed with windows base application to cater the serialization requirement. Serialization software with online print, verify and aggregation systems as per GS1 /country specific guidelines for different level of packing Primary, Secondary, Secondary – II, Tertiary & Palletization.

Main Screen

rTRACKER Line Manager

SYSTEM LICENCE TO: DEMO SOFTWARE	PLANT ID : Russia	CURRENT US : a
	LINE ID : Imulex line (1083)	USER ROLE :
	DATE : 05/09/2018	LOGGED IN TIME : 12:46:13 PM

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DASH BOARD

PACKAGING LEVEL	PRIMARY	SECONDARY	SECONDARY-2	SECONDARY-3	TERTIARY
GTIN					
QUANTITY					
PRINTED					
VERIFY					
ACCEPTED					
REJECTED					
SAMPLE					
PC MAP					
MAPPED					
MAPPING					
MAP FAIL					
STATUS					

BATCH INFORMATION

JOB NAME : <JOB NAME>

PRODUCT NAME :

BATCH NO :

MFG. DATE :

EXP. DATE :

NDC/PC :

All the activities at every level from single screen which can control remotely as per the IT policy defined and configure by customer.

Graphically animation of live screen is available to view each module status batch wise, UID used at each module, Rejection Ratio, Current status and pending job.

Software

- Line manager is designed on windows based software
- Main Function is to communicating with different packaging level of module in production line depend on packing level required at the time of packing.
- User friendly protocol for integration with ERP
- Level 4 and 5 software solution provider can push or pull data directly from Line manager depend on architecture of software solution in flat files
- In case of Enterprise Server and multiple plant at multiple location with multiple production line the Line Manager (CSPL LM), capable to communicate
- Line Manager take the batch details from source like level 4 and 5 software solution provider or enterprise Server
- Present Global Serialization support for country compliance
- Multiple level of packing is configured at Line Manager
- All the activities at every level from single screen which can be control remotely as per the IT policy defined and configure by customer
- Different packaging level UID/SSCC will be allocated to different module in the production line
- Can support different language for user friendly requirements
- Module add or remove from the line as per change in pack style or number of packing level is easy to configure at Line Manager
- Data Input options are, flat file (Net folder), from Level 4/5 or from ERP system

- Job Creation
- Job Start and Stop
- Change of partial batch or re-allocation
- Up-Stream & Down-stream configuration
- Upgradable to future requirement by adding additional Drivers without changing Hardware
- XML file generation as per countries guidelines
- Batch summery report generation
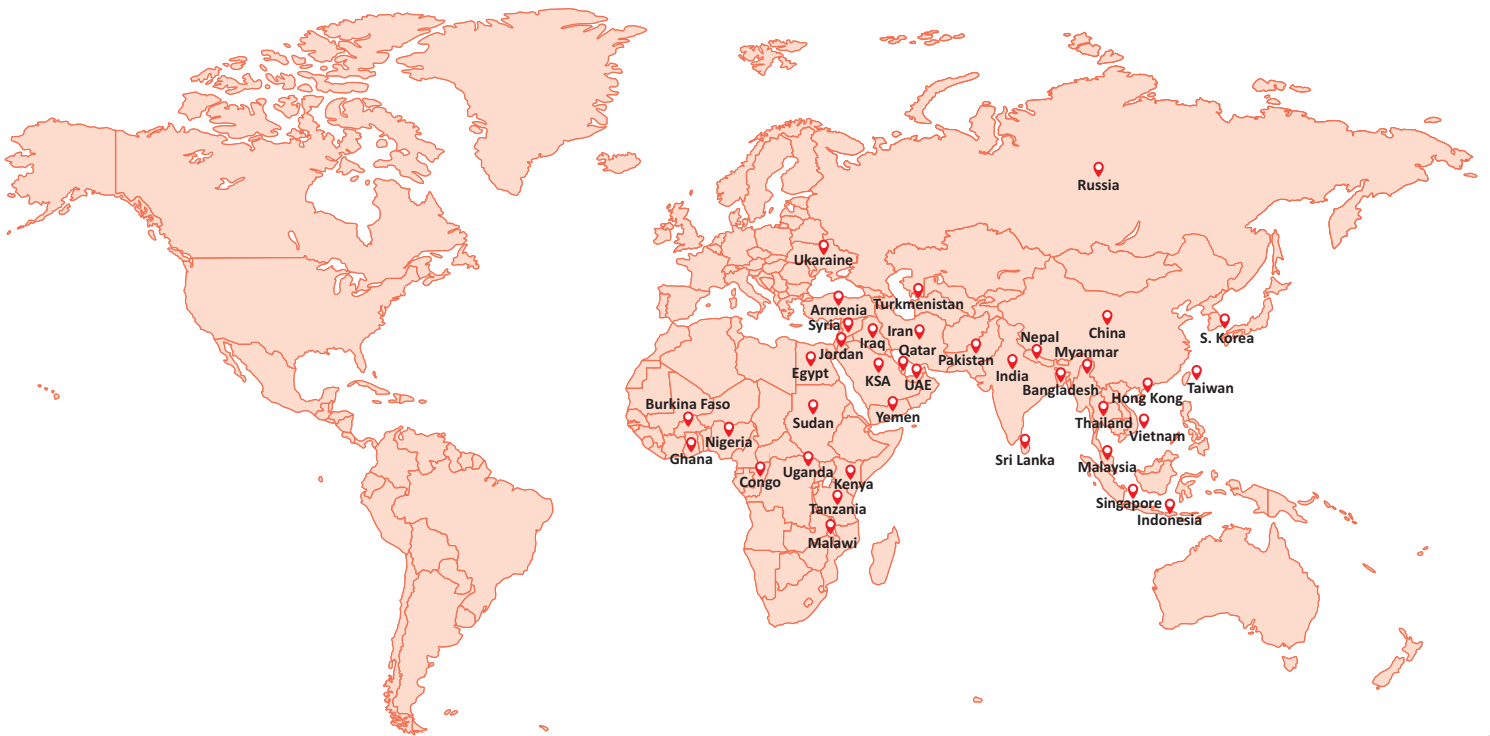- Batch Details report generation (Parent-child)

Operation

- **Sampling:** To take the specimen for QC, Production, Shift change over etc...........
- **Replace UID:** Replacement of UID is possible in case of damage or other operational needs even after aggregation but before batch close
- **De-aggregation:** Due to any reason if De-aggregation required for aggregated data for further process can be manage from CSPL LM
- **Reprint:** We can reprint the aggregated label in case of label damaged by using the High level authority
- **De-commissioning:** Damaged UID can be destroy during the production due any reason
- **Suspend Job:** Suspension of job in case of break down, data can be transfer to next packing line or to Level 4/5, ERP or Net folder
- **Close Batch:** For final batch / XML report generation after completion of Batch

GAMP 5 Validation Documents List
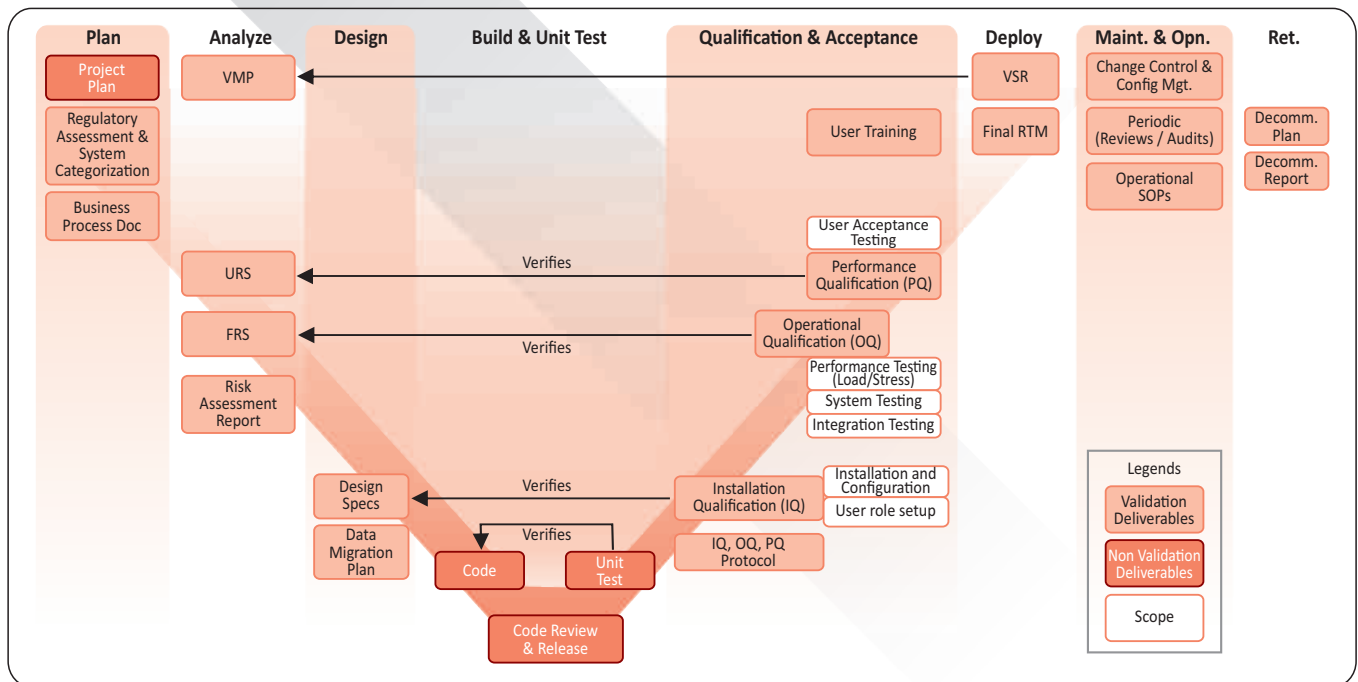
1. Validation Plan (VP)

2. Risk Assessment Plan (RAP)

3. Risk Assessment Report (RAR)

4. Good Manufacturing/Production practice (GxP)

5. Functional Risk Assessment Report (FRA)

6. 21 CFR Part 11 Assessment (21 CFR)

   - 21 CFR Part 11 assessment template

   - Discrepancy template

   - FRA for serialization system Template

   - GxP assessment for serialization system template

   - Protocol Template

7. Design Qualification (DQ)

8. Installation Qualification (IQ)

9. Operational Qualification (OQ)

10. Performance Qualification (PQ)

11. Traceability Matrix Template (TM)

12. Validation Summary Report (VSR)

Global Presence