THE FUTURE OF CONTAINER-LEVEL TRACEABILITY FOR PREFILLABLE SYRINGES

In this article, Sam Eubanks, Vice-President of Software Development, and Hervé Soukiassian, Associate Director, R&D Project Management, both of BD Medical – Pharmaceutical Systems, discuss the BD traceability solution. This concept under development aims to deliver traceability at the unique container level from manufacture to the point of care.

Pharmaceutical companies must address a triple challenge: ensuring compliance to serialisation mandates[1,2] and assessing new digital technologies to augment manufacturing efficiency and safety,[3] all while keeping an eye on tomorrow's factory-to-point-of-care (POC) traceability requirements.[3] BD proposes a way forward on all three challenges, starting with container-level traceability for fill-finish operations for prefillable syringes (PFSs).

Serialisation directives are now in place in more than 30 countries, mandating greater visibility and accountability for drug product custody along supply chains.[4] However, existing serialisation solutions limit traceability to the saleable unit level only (i.e. the secondary packaging),[1,2] leaving a door open for falsified or poor-quality medicines to make their way to the point of consumption (pharmacy retail shelves, hospitals and patients). There are also implications further upstream. Because the PFS is associated with the secondary packaging only at the end of the manufacturing line, in these cases, serialisation cannot contribute to preventing and sorting out mix-ups earlier in the fill-finish process. This represents a missed opportunity.

BD, a leading provider of drug delivery solutions, has teamed up with industry-leading partners in tagging and traceability technologies to develop a comprehensive solution that goes beyond compliance to deliver traceability at the unique container level. The goal of the programme is ultimately to ensure the integrity of the drug product at the point of consumption through a unique combination of device tagging, supply chain tracking and end-user/patient authentication.

In a first phase, the BD traceability solution will concentrate on applying the advantages of unique container-level traceability to pharma manufacturing operations. Subsequent phases will consist of expanding container-level traceability beyond pharma fill-finish operations to cover distribution and the POC.

OVERVIEW OF THE BD TRACEABILITY SOLUTION CONCEPT

With the BD traceability solution concept, ready-to-fill syringes will incorporate a unique identifier (UID) using either data matrix or radio frequency identification (RFID) technologies. At the end of the manufacturing process at BD, tagged syringes will be sealed into tubs and their UIDs will be read and aggregated to the tub/nest ID in an encrypted database. This aggregation of parent and child units will ensure tag readability prior to delivery to the customer filling line and will establish both data integrity and syringe pedigree.

When the syringes are loaded onto customer filling lines, one scan of the tub/nest ID will be enough to associate it with

Sam Eubanks
Vice-President of Software Development
E: sam.eubanks@bd.com

Hervé Soukiassian
Associate Director,
R&D Project Management
E: herve.soukiassian@bd.com

BD Medical – Pharmaceutical Systems
11 rue Aristide Bergès
38800 Le Pont-de-Claix
France

www.bd.com

"As the product moves out of the manufacturing site and down the supply chain, a serialised pedigree of the combination drug product can be created in a secure, fully encrypted cloud-based repository."

the current batch. Each unique syringe ID will therefore be associated to the product filling batch and API code. This is meant to accomplish three goals:

- Ensure compliance to 21CRF 610.14 US FDA General Biological Products Standards[5]
- Establish a permanent link between syringe and API
- Enable the segregation of batches.

At each subsequent process step, the syringe ID can be cross-checked to prevent mix-ups. The process is not expected to impact the overall equipment efficiency of the production line. Industry-leading hardware and software solutions will provide the capabilities to access syringe container ID and ensure ease of integration at the customer site.

A cloud-based data exchange and management system will ensure linkages between the unique container ID and the serialised drug product. As the product moves out of the manufacturing site and down the supply chain, a serialised pedigree of the combination drug product can be created in a secure, fully encrypted cloud-based repository.

At the end of the process, when the patient or caregiver is ready to administer the medication, a final query can be made to confirm the drug's clean pedigree and authenticity, based on its unique movement through the pharmaceutical supply chain.

BUILDING VALUE BEYOND COMPLIANCE

The BD traceability solution is expected to enable precise, unit-level visibility with the potential to log the container's passage through each manufacturing step. This data – which can include the individual container's manufacturing information – will endow production managers with unique tools to help in process improvement as well as preventing and resolving issues accurately and efficiently.

The BD traceability solution is designed to provide a verifiable pedigree from manufacture to the POC. This pedigree will be based on a chain of custody record building upon the immutable core of the container's UID.

A TURNKEY SOLUTION FOR TRACEABILITY DURING THE FILL-FINISH PROCESS

The BD traceability solution is expected to address the following customer needs:

Mix-Up Prevention

Mix-ups carry a hefty price tag in terms of staff time and lost product.[6] For example, a syringe might be filled with a different drug from the one mentioned on the label. Colour-coded label rings are limited to their ability to distinguish multiple drug products, and they cannot distinguish batches, especially if the mix-up occurs before the labelling step. BD pretagged syringes carrying serial numbers should help to prevent mix-ups and resolve queries prior to, during and after the manufacturing process.

Enable Batch Segregation

The BD traceability solution is expected to provide manufacturers with unit-level visibility of key manufacturing processes by giving production line managers precise data on the position and time of each unit at each stage of the production process. This should enable rejected units to be traced back precisely to each discrete step of the fill-finish operation. Such accuracy is meant to help limit batch segregation to affected units only, which, in turn, could reduce the costly tendency to over-segregate or dispose of an entire batch due to limited process visibility. By optimising investigations and batch segregation, the solution is expected to help maintain the continuity of production.

"The BD traceability solution is expected to provide manufacturers with unit-level visibility of key manufacturing processes by giving production line managers precise data on the position and time of each unit at each stage of the production process."

Speeding Reconciliation and Line Clearance

The BD traceability solution is meant to provide unit-by-unit accountability for every container on the filling line, the batch it belongs to, its status (i.e. successfully filled, rejected, etc) and potentially other information, thus automating reconciliation and accelerating line clearance. It will help ensure that no container is left behind when a new batch starts up.

Faster Quality Assurance Investigations

The BD traceability solution is meant to accelerate quality assurance (QA) investigations when process deviations or other issues arise during the fill-finish process. Having syringe traceability data to hand would enable investigators to link issues to the specific containers and batches concerned. As more than one batch of syringes may be used to produce a single batch of a finished product, the BD traceability solution should help investigators limit the number of finished product batches requiring investigation – which should significantly limit the number of batches affected in the case of an expanded-scope investigation.

Effective, Targeted Action in the Case of Recalls

Product recalls, whether they concern a medication or a medical device, typically require casting a wide net to ensure that a potentially harmful product has been fully eliminated from the market. The BD traceability solution is expected to provide QA/quality control teams with a high degree of precision in identifying the units or batches to be recalled. This is expected to help companies work rapidly and proactively to locate recalled units and issue product withdrawal orders to appropriate parties, preventing the products progressing further down the supply chain.

Compliance

The BD traceability solution incorporates industry best practices as defined by GS1.[7]

"The BD traceability programme is focused on delivering reliable execution and end-to-end, cost-effective implementation of device, hardware and software development, installation, on-site validation and maintenance."

BD TRACEABILITY SOLUTION EXPECTED TO HELP DE-RISK YOUR TRACEABILITY INVESTMENT

With hundreds of pharmaceutical and biotechnology companies placing their confidence in its products, BD is a natural partner for the provision of serialised syringes.[8] The company offers an open platform solution, aimed at meeting customer requirements for RFID or data matrix technologies and the accompanying software. The BD traceability programme is focused on delivering reliable execution and end-to-end, cost-effective implementation of device, hardware and software development, installation, on-site validation and maintenance.

By choosing the BD traceability solution and the automatic identification and data capture technologies and standards they incorporate,[7] pharmaceutical companies will ensure that compatibility and interoperability will be maintained even as technologies evolve. As a container supplier, BD is well positioned to support new data use cases with manufacturing data related to container UID.

The BD traceability solution draws on the expertise of the BD Software Technology Solutions (STS) team, comprised of 1,500 software engineers that partner with BD business units to design, develop and commercialise integrated solutions. STS provides software solution delivery, technology platform harmonisation and solution development services.

GOING FORWARD

BD would like to help pharma customers transition their manufacturing lines to unit-level traceability with a coherent path towards end-to-end traceability. BD is working to provide a comprehensive solution that provides proven, industry-leading technologies along with the industry know-how and support of a world leader in PFS technology.

BD proposes to partner with customers interested in this comprehensive traceability solution. This will allow interested customers to specify the use-case requirements to be built into the solution, and test the tagged syringes, production line hardware and software in a pilot project.

ABOUT THE COMPANY

BD is a large, diverse, global medical technology company. Its Medical Pharmaceutical Systems division is the world's largest syringe manufacturer. It offers PFSs, self-injection systems, safety and shielding solutions, and needle technologies and associated pharma services.

ABOUT THE AUTHORS

Sam Eubanks is a Vice-President of Software Development at BD, responsible for the design, development and lifecycle management activities for enterprise software solutions. He has over 23 years of experience in the software industry across various vertical markets, the last 18 of which have been within the healthcare industry. Mr Eubanks joined BD in 2015 and has led the delivery of cloud-based, deployed and mobile-enabled enterprise solutions for multiple business units. He has also led innovation and delivery for multiple enterprise software platforms, which support informatics solutions in the areas of interoperability, mobility and remote support and service. Prior to joining BD, Mr Eubanks worked at CareFusion, and at multiple software start-up companies and consulting organisations, including PricewaterhouseCoopers. He holds a BSc in Civil Engineering and an MBA.

Hervé Soukiassian joined BD Medical – Pharmaceutical Systems in 2007 and is currently managing product development of PFSs for the chronic segment, within R&D. Under his leadership, BD Neopak™ XSi™ and the BD Neopak XtraFlow™ platforms have been successfully developed and brought to market. He also contributes actively to industry initiatives such as the PDA task force and has co-authored several recently published technical papers. Prior to joining BD, Mr Soukiassian was at Hewlett Packard for 13 years in positions of increasing responsibility, developing expertise in the fields of process engineering and product development. He was also a member of the board of directors of ActiCM, a start-up company specialising in optical co-ordinate measurement machines. Mr Soukiassian graduated from the Institut National des Sciences Appliquées in Lyon (France) as a mechanical and industrial engineer, with an MA in Material.

REFERENCES

1. *"Drug Quality and Security Act (DQSA)". US FDA, November 27, 2013.*
2. *"Falsified Medicines Directive" (2011/62EU). EU, July 1, 2011.*
3. *"Industry 4.0: Reimagining manufacturing operations after COVID-19". McKinsey & Company, Jul 2020.*
4. *"Policy paper on traceability of medical products". World Health Organization, Aug 2020.*
5. *US Code of Federal Regulations, Title 21 (Food and Drugs), Chapter I (Food and Drug Administration Department of Health and Human Services), Subchapter F (Biologics), Part 610 (General Biological Products Standards), Subpart B (General Provisions), Section 610.14 (Identity).*
6. *"Supporting Becton Dickinson in assessing the opportunity for industrial traceability solutions". Study conducted for Becton, Dickinson and Company.*
7. *"GS1 Standards Document: Global Traceability Standard for Healthcare: Business Process and System Requirements for Supply Chain Traceability". GS1, October 2013, Issue 1.2.0.*
8. *Data on file at BD (IQVIA-based analysis and BD internal systems SAP ECC, SAP Legacy, Tracis, Nodum). 2016 update.*

THE DIFFERENCE OF ONE DRUG DELIVERED

WITH A GLOBAL LEADER IN PREFILLABLE DELIVERY SYSTEMS. BD partners closely with leading pharmaceutical companies to support their success from drug development to launch and beyond. With a broad portfolio of innovative drug delivery systems, a global perspective and regulatory insights, a BD Medical–Pharmaceutical Systems team can partner with you to match the optimal solutions to your product. In addition to prefillable syringes, our technologies include self-injection systems, safety and shielding solutions—which we can customize and develop to meet your precise technical requirements and the demands of your business. You can also count on our depth of regulatory knowledge, product development, medical expertise and responsive support. Discover the confidence of working with the right partner. **Discover the difference of BD.**

Learn more about the Difference of One at drugdeliverysystems.bd.com

BD

Advancing the world of health