Digital Technology, an essential enabler to meet the burden of a pandemic, and Beyond…

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Outline

Business Continuity Challenge

Communication, Collaboration, Inspection experience

Adapting to changes in drug treatments

Digital Technologies for faster information flow and enhanced Patient Safety

Towards New Ways of Regulatory Affairs

Concluding Remarks
**Business Continuity Challenge**

**From a big challenge**

**To new approaches to our work**

**Safety First**
- Working from home for all non-lab/Mfg operations
- Adaptation to the state & local Directives, with on-site occupancy, testing and tracing

**Manufacturing & testing operations**
- Adapted scheduling and safety protocols, including social distancing measures, new prioritization & segmentation of work

**Uninterrupted global supply to patients**
- Managing challenging logistics of global distribution
- Adapting to changes in treatment (more home-use)

**Ways of Working**
- Maximizing the use of digital communication and collaboration technologies, and the use of advanced data analytics

**Speed for all COVID-related activities**
- “Faster than Fast”
RealWear Head Mounted Tablet combined with Zoom conferencing to support **remote hand-free** collaboration as “**Telepresence Stack**” for:

- **Training**
- **Tech & Method Transfers**
- **Troubleshooting**
- **Remote Internal & Cross-company audits**
- **Inspections**: walkthrough or on-demand tour

**Benefits**

Supporting “business continuity”, personnel safety & faster access to experts.

Easy deployment
Inspections during a pandemic

Flexible, Adaptable

- Fully remote/virtual or
- Hybrid with one inspector on site and others remote

Different approach to inspection management and inspection logistics
- Global manufacturing and laboratory facilities are under different local safety directives (social distancing, scheduling, testing)
- Global travel restrictions
- Use of a wide range of communication technologies
Adapting to changes in drug treatments and clinical priorities

To reduce risk of COVID exposure in clinics while maintaining treatment compliance

Changes in administration (Intra-Venous to Sub-Cutaneous, combination, faster administration) and/or use environment (clinic vs home).

Considerations:
- Human factors: users, environment, instructions, medication errors, new dose
- Product quality: additional in-use stability data; product combinations
- Microbial control

Accelerate and expand access
⇒ New INDs/IMPDs
⇒ Acceleration of global reviews
⇒ Supply “Direct-to-Patient”

Leveraged HA Guidances on conducting clinical trials, supporting availability of medicines during COVID-19 Pandemic
Patient-Centric control strategy

*Increasing speed and insights*

Increasing speed and gaining deeper insights in connecting clinical output to the product quality profile.
- Global digital solutions for connecting multiples systems and datasets
- Setting up new advanced data analytics

**Benefits**
- Shorten analysis time, authoring, internal review/compliance checks
- Set more patient-centric specifications
- Enable lifecycle management
- Increase overall understanding and insights
Paperless Product Information (ePI)

To provide the latest information on a medicine’s safety and conditions of use

Real-time product information update to the healthcare provider and/or patient at the point of care

- Faster deployment of the latest authorized product label information: new safety consideration, expiration dating, new mode of administration
- Easier to access
- Easier to read

ePI information can flow to other systems, such as electronic health records and e-prescribing systems
Patient Safety

Verification of Product Identity

Positive Verification

✔ Possibility to select the criteria to be verified (SN + GTIN, Expiration date, etc) with country-specific information

✔ The user sees basic information about the medicine & contact information

Negative Verification

❖ Wrong or adulterated product
❖ The user is provided contact information.
Patient Safety

*Track & Trace of digitized products*

**Product Integrity**
- Identification of the product at point of care leveraging serialization (mitigation for errors & counterfeiting)
- Assurance of shipping condition within authorized parameters

**Product location**
- Geo-localization of the product
- Anticipating shortages
- Triggering replacement
- Adjusting distribution faster to the demand

Towards a more secure and predictive supply chain and a reduction of counterfeited medicines and expired lots
New “nuts and bolts” in the Industry

How we develop the product and process understanding and enhance it

• Process automation, Robotics, Sensors
• Data: accessibility, connectivity of systems, data standards, real-time monitoring
• Documentation: Lab notebooks, automated reporting
• Knowledge management, training
“Nuts and bolts” of the Future

Data-Based Submission

Current
• e-paper submissions
• Static data shared at pre-defined stages (country specific)
• Range of data repositories

Tomorrow
• Harmonized structured data standards with global accessibilities
• Global parallel reviews or Increase reliance approach
• Rolling cloud-based data-submissions (i.e. Stability, Process Verification) with dynamic regulatory assessments
• Data analysis standards
• Other…
“Nuts and bolts” of the Future

Data-Based Submission and Cloud-Based Regulatory Ecosystem

Federated Data Infrastructure for Europe
To create an open, digital ecosystem to make data available, securely collated and shared in a trusted manner

Joint venture of 10 large Pharma companies to develop a cloud submissions platform in collaboration with global health authorities
Accumulus.org

Sponsors

Health Authorities

Real-world (HCP, patients)
Digital Technologies are essential to support business continuity, facilitate global collaborations and faster access to data and critical information.

In the short term, there are significant opportunities to maximize the value of digital technologies for faster access to real-time product information through e-labelling and, to ensure Product Safety around the world.

Bigger opportunities lay ahead within the regulatory field to accelerate submission & review processes, enhance transparency and collaboration... to bring innovative medicines to patients faster.

*Thinking Big, Starting Small, Together*
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