How the PI System Helps Sandoz to Cope with Regulatory Compliance

Presented by Alexander Haimayer
Head Data Systems
Sandoz GmbH Kundl/Schaftenau

SANDOZ
a Novartis company

Agenda

- Sandoz – a Novartis company
- The PI System at Sandoz
- The role of a health agency
- Regulative aspects

SANDOZ
a Novartis company

Generics – Good News for Everyone

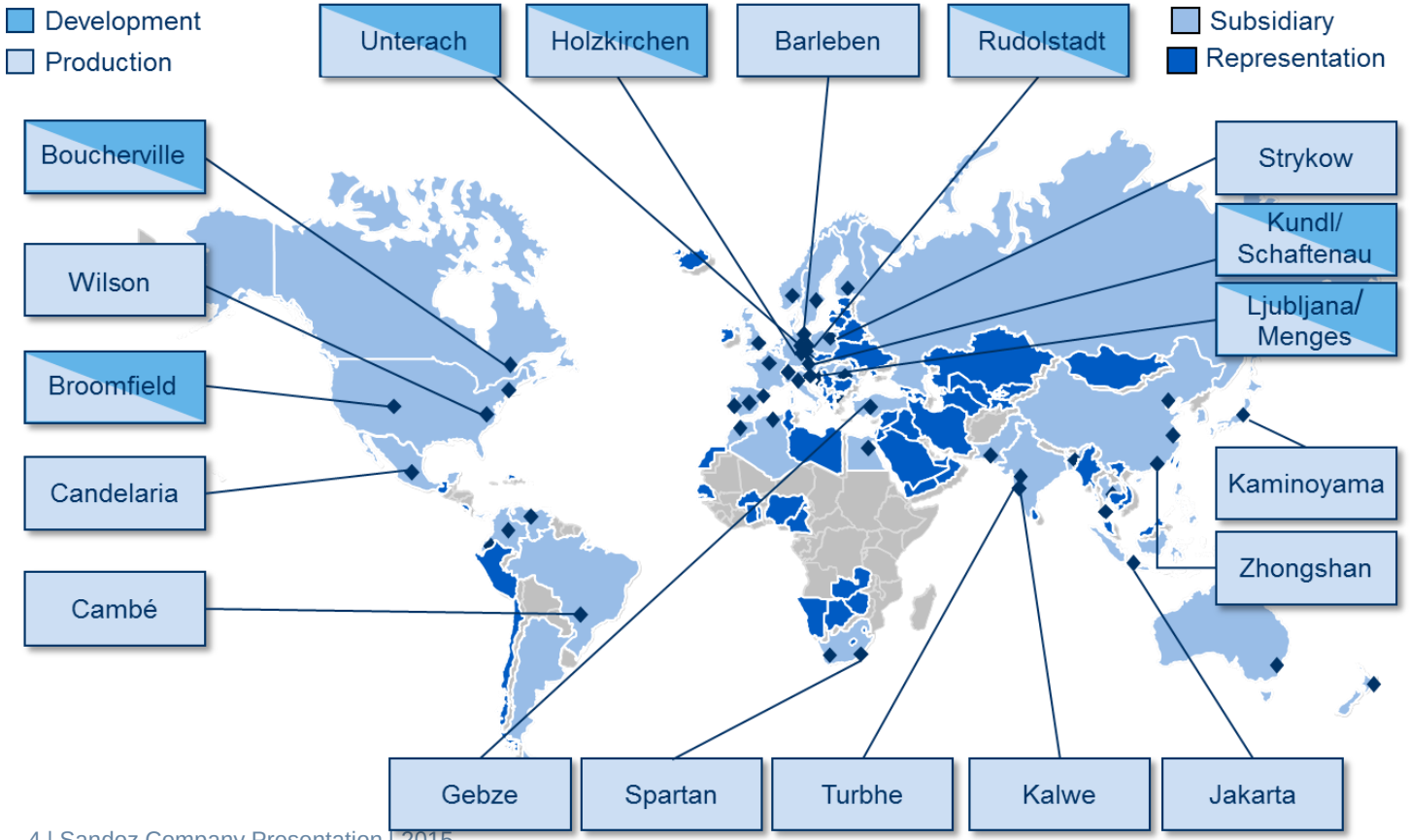
Significantly increase global access to high-quality and affordable medicine

Enable enormous cost savings for patients and healthcare systems

Free up funds for patent-protected medicines and drive further innovation

SANDOZ
a Novartis company

Sandoz is active in more than 160 countries



SANDOZ
a Novartis company

Sandoz GmbH, Kundl

Largest research and development site of Sandoz worldwide

Kundl (Tyrol, Austria)

- Fermentation
- Synthesis (ß-lactam antibiotics)
- Sterile precipitation (ß-lactam antibiotics)
- Enzymes
- Recombinant proteins
- FDFs
- Pilot plants (fermentation, downstream and chemical synthesis)

SANDOZ
a Novartis company

Sandoz GmbH, Schaftenau

Center of Competence for modern cell culture technology

Schaftenau (Tyrol, Austria)

- Synthesis (non-ß-lactams)
- Sterile precipitation
- Lyophilization
- Hormones, anticoagulants
- Recombinant proteins (cell culture technology)
- FDFs

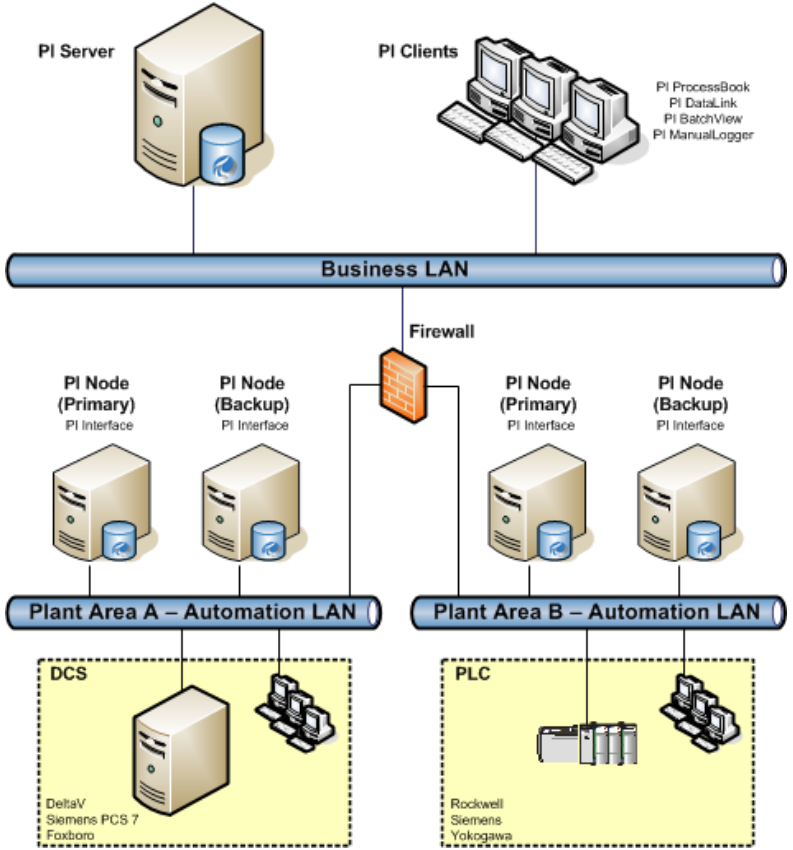
SANDOZ
a Novartis company

Agenda

- Sandoz – a Novartis company
- PI-System at Sandoz
- The role of a health agency
- Regulative aspects

SANDOZ
a Novartis company

The PI System at Sandoz Kundl/Schaftenau



Area of operation:

- Data Archiving
- Process Monitoring
- Data and Fault Analysis
- Batch Data Recording (EBR)
- Calculations
- Monitoring (e.g.Refrigerators)

Key data:

- First Installation 1996
- >150.000 PI Tags on 5 PI-Servers
- >1500 Users at Site
- > 60 PI Interfaces

SANDOZ
a Novartis company

Agenda

- Sandoz – a Novartis company
- The PI System at Sandoz
- The role of a health agency
- Regulative aspects

SANDOZ
a Novartis company

The role of a health agency

SANDOZ
a Novartis company

The role of a health agency
Food and Drug Administration

Mission statement:

The agencies mission is to **ensure** the **safety** and **effectiveness and security** of the products under its jurisdiction.

- The Food and Drug Administration (FDA) is an agency within the U.S. Department of Health and Human Services.
- It is protecting the public health by **assuring the safety, effectiveness, and security** of human and veterinary drugs, vaccines and other biological products, medical devices, nation's food supply, cosmetics, dietary supplements, and products that give off radiation.
- FDA attempt to ensure compliance by adverse reporting, field alert reports, inspections, market sampling, recall oversight and analyzing industry, technology and trends.
- FDA focusses on risks and GMP (Good Manufacturing Practice) concerns.

The role of a health agency
Types of inspections

Routine Surveillance Inspections

- **Periodic**
  frequent (usually every 2 years) inspections to ensure continued compliance after a product has been launched or for complex production site
- **Risk Assessment Model**
  i.e. Center for Drug Evaluation and Research: Risk value assigned (date since last inspection, classification of last 3 inspections, recalls, therapeutic significance)

Directed Inspections

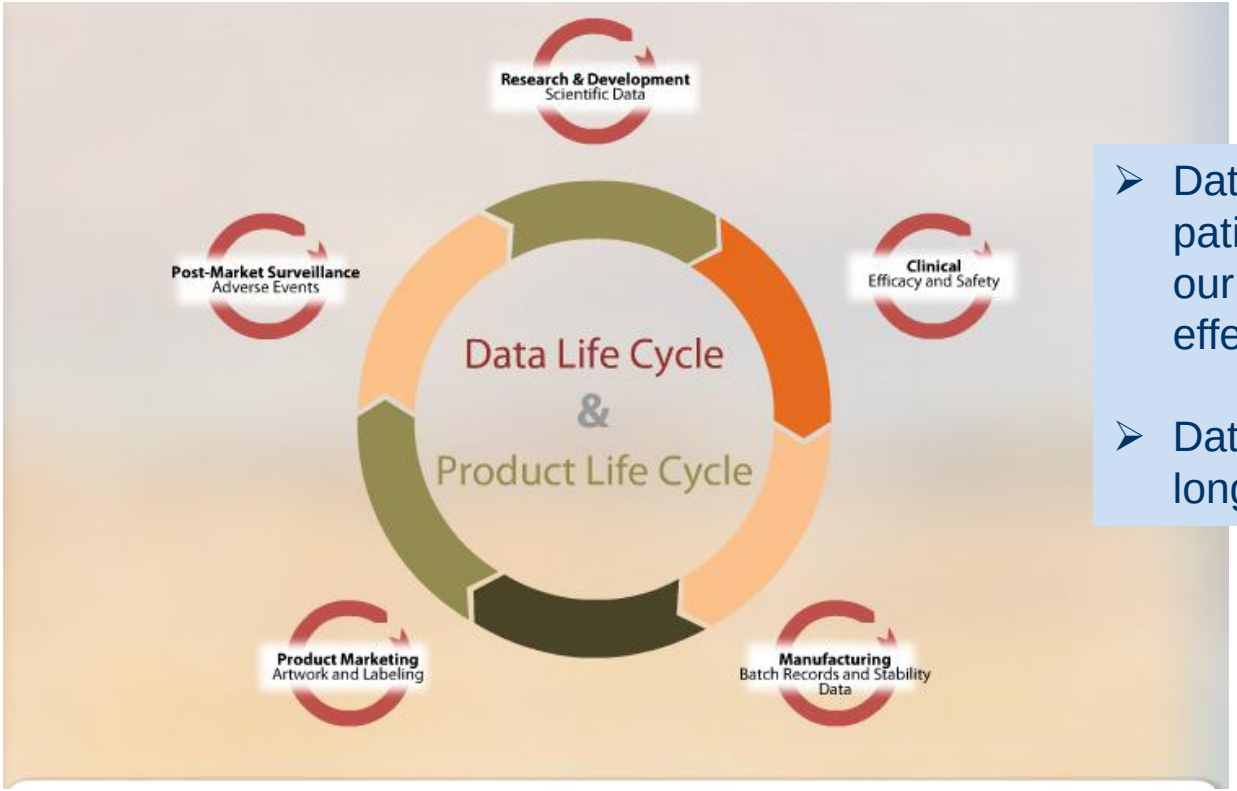
- **Pre-Approval Inspections (PAI)**
  The New Drug Application (NDA, ANDA) is the registration file sent to the FDA for marketing of a new drug product in the USA.
- **For-cause-inspections**
  non-compliance situation e.g. follow-ups of previous inspection findings, recalls, complaints or any product related incidents

Agenda

- Sandoz – a Novartis company
- The PI System at Sandoz
- The role of a health agency
- Regulative aspects

SANDOZ
a Novartis company

Data Integrity
Data Lifecycle & Product Lifecycle



- Data is the evidence to our patients and health authorities that our products are safe and effective.
- Data tells the story of a product long after it is shipped.

SANDOZ
a Novartis company

Data Integrity
The PI System and Data Integrity

Example scenario:
Periodic Inspection of a FDF production line (Finish Dosage Forms) by a regulative authority.

Expectation:
Generated data needs to be complete, accurate, consistent, accessible and secure.

Does the QA review data matches the electronic data?

- Regulators want to see the data directly in the system

How did you get the data?

What data is changed (Audit Trail)?

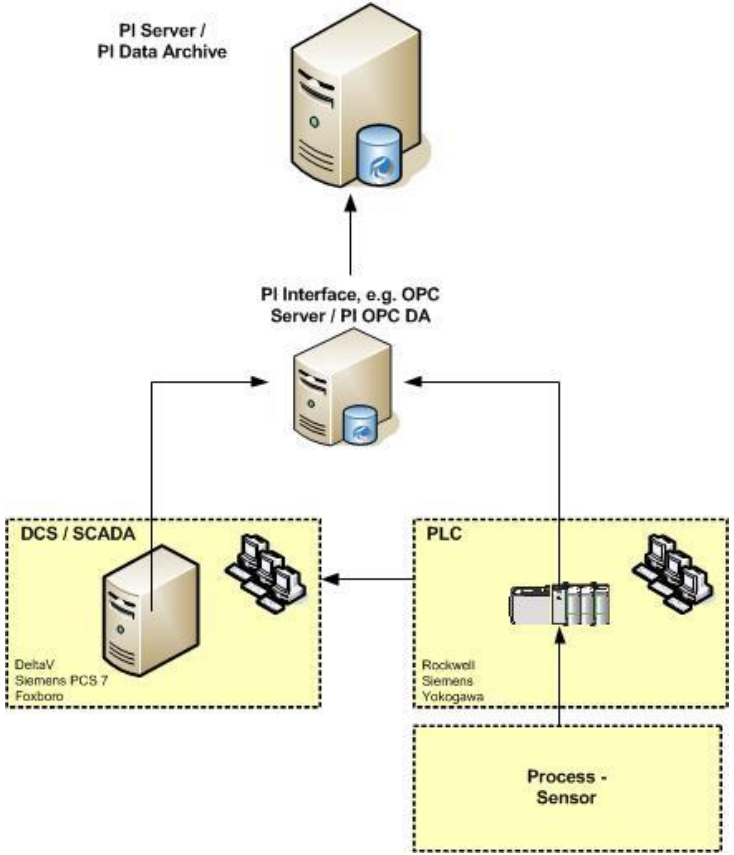
What was the flow of data?

- Regulators don‘t want to only see the end result anymore:

  - Audit Trail for configuration and data changes
  - Security Management
  - Segregation of duties

SANDOZ
a Novartis company

Data Integrity
The PI System Data Exception & Compression



- Concept for PI System data archiving. This concept should be explainable in regulatory inspections.
- First priority: archive all relevant GxP Data (apply filtering carefully).
- Align filtering to data recording in the DCS/SCADA system.
- Terms for data archival:

  - *Exception:* filtering at interface node
  - *Compression:* filtering at PI Data Archive

SANDOZ
a Novartis company

Archiving
The PI System for Longtime – PI Data Archive

Example scenario:
Raw data archiving of particle sensor in a FDF sterile filling unit (Finish Dosage Forms).

Expectation:
Production relevant data is archived and accessible for a specific time period. Raw data (PI System data) is part of electronic batch record.

How do you know that access to data archive is ensured?

- Regulators ask for Backup and Recovery procedures for the system

Is archived data complete?

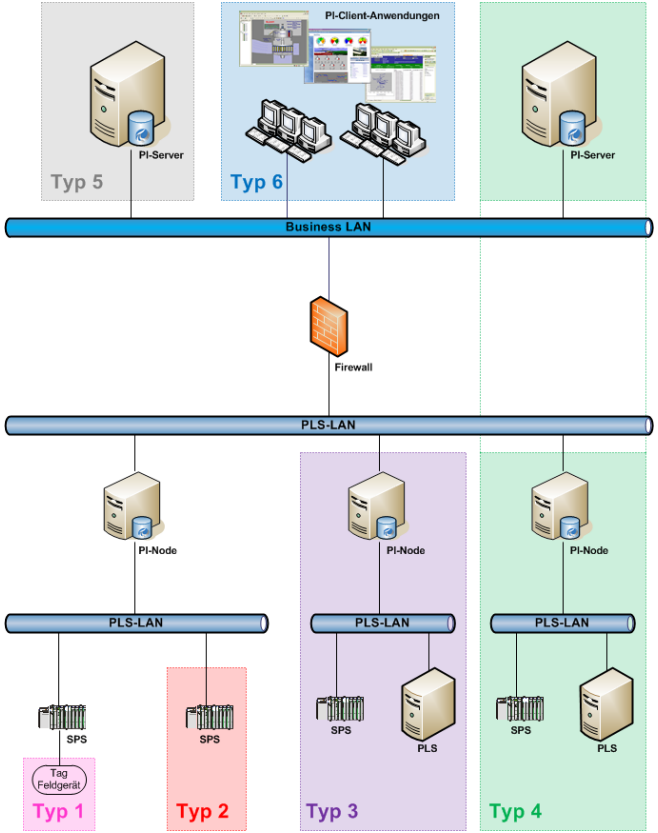
Are there any deviations?

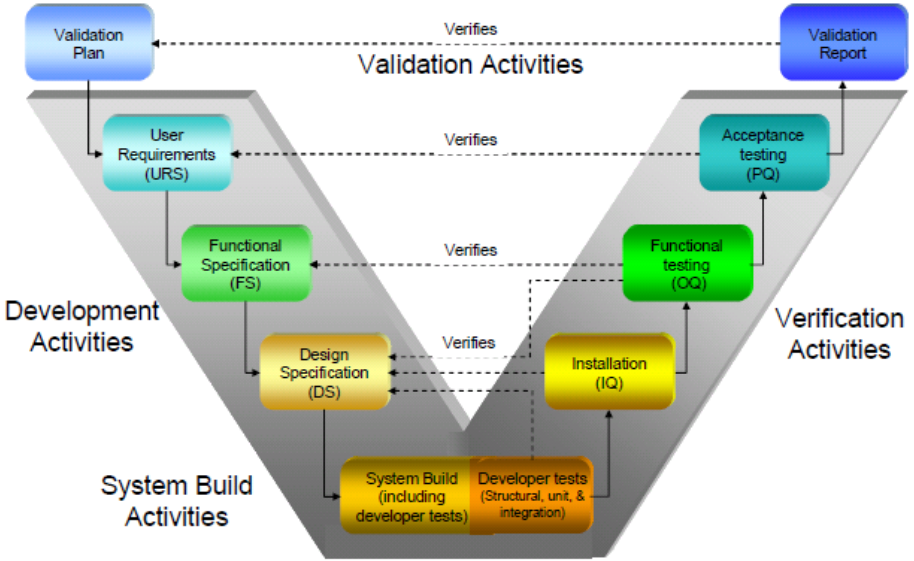
- Regulators want to see documented evidence e.g. of:

  - Incident management
  - Deviation handling
  - Product impacts

Validation

CSV – Computer System Validation





Note that the grey-shaded background represents the classical boundaries of the V-model

SANDOZ
a Novartis company

Validation

The PI System CSV – Lifecycle Management

Scenario:

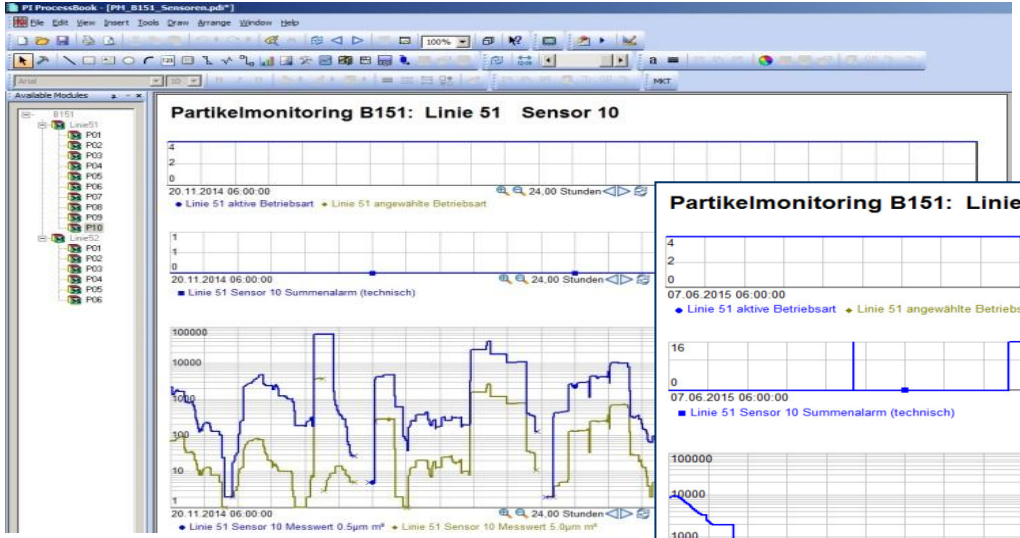
Monitoring of particles in the sterile filling line of non-solid FDFs (Finish Dosage Forms).

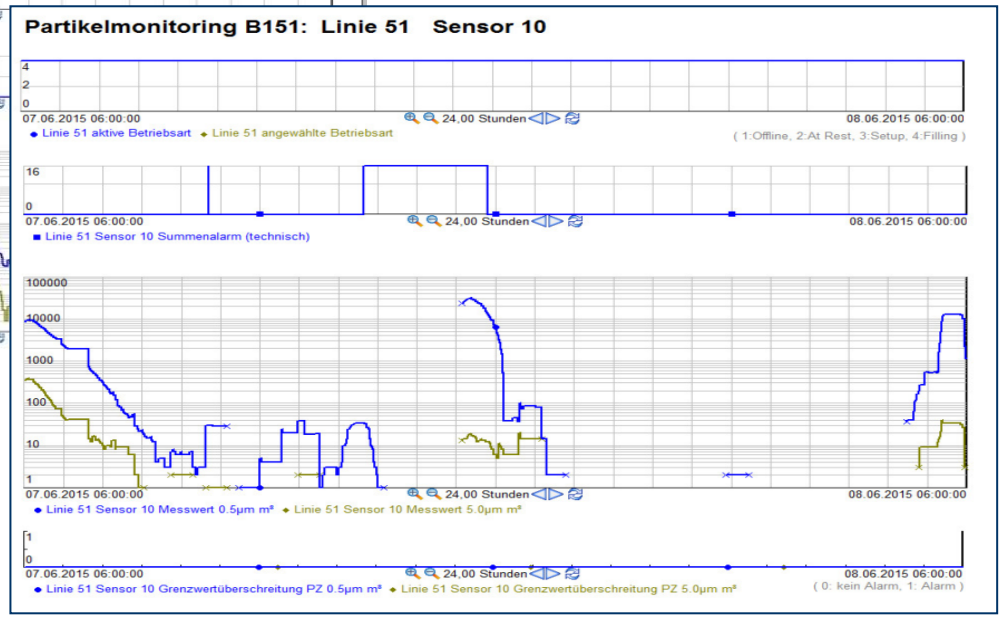
- Function Risk Assessment (FRA) for the identification of potential risks
- Change Management
- Incident and Deviation Management
- User Management
  - access rights
  - segregation of duties)
- Disaster & Recovery procedure/tests

SANDOZ a Novartis company

Validation

The PI System CSV – Lifecycle Management





SANDOZ
a Novartis company

How the PI System helps Sandoz to cope with regulatory compliance

In the regulated production environment, data is the evidence to our patients and health authorities that our products are safe and effective.

Therefore, IT-System are an integrated part for the development, release, production and post-market surveillance within a product life cycle.

SANDOZ
a Novartis company

Business Challenges

- High Focus on regulatory requirements, also for IT-Systems (e.g. Data Integrity).
- Data are part of the (electronic) batch record.
- Only one archive for GxP production raw data at site.

Solution(s)

- The PI System as the site-wide data Infrastructure implemented for a defined data archiving strategy.
- Sophisticated and stable technology, processes and systems deployed with the PI System.

Results and Benefits

- System with good standing within our GxP production environment as a standard for raw data archiving at a large production site.
- As a consequence, good inspection results because of a clear story.

SANDOZ
a Novartis company

Contact Information

- Alexander Haimayer
- alexander.haimayer@sandoz.com
- Head Data Systems
- Sandoz GmbH Kundl/Schaftenau

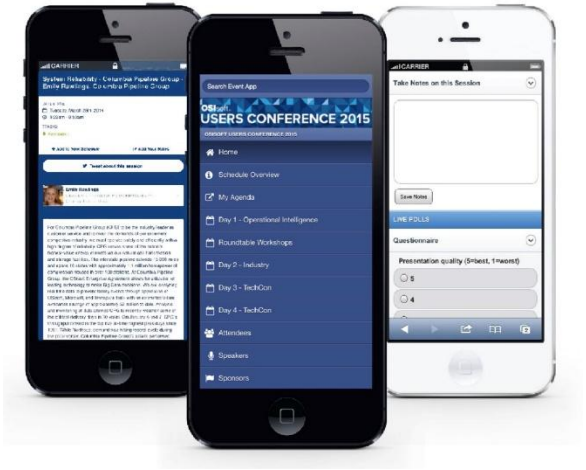
Questions

Please wait for the **microphone** before asking your questions

State your
name & company

Please don't forget to…

Complete the Online Survey for this session



http://eventmobi.com/emeauc15

감사합니다

谢谢

Danke

Gracias

Merci

Thank You

ありがとう

Спасибо

Obrigado