Roche Diagnostis IT Solutions Deployment of Software

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Agenda

• Product Overview
• The Challenge of Safe and Effective Products
• The Product Design Process
• Software Deployment
  – Tasks, Challenges
  – Processes and Activities
• Summary
cobas IT in the sample workflow
IT solutions managing the IVD lab processes

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Goal of Risk Management

Avoid hazards caused on people’s life by products.
Which product risks need be considered?

Product Risks

Direct Risks
- Personnel
- Environment

Indirect Risks
- Patients
Motivations behind Risk Management

- Risk Management is a Regulatory Requirement
  - Avoid hazards
  - Indicate proper product use and state residual risks

- Risk Management is one of the few means to prioritize and rationalize effort and gain efficiency during V&V and development in a regulatory compliant way. Risk defines the:
  - Test intensity and amount of objective evidence
  - Level of detail of design documentation

Provide Customers with Safe and Effective Products
Regulatory Context

• Risk Management is mandatory for IVD products (FDA requirement)

• We comply to the International Standard ISO 14971 “Application of risk management to medical devices”
Design Control for Product Development

- **Analysis**
- **Feasibility**
- **Development**
- **Implementation**
- **Manufacturing**
- **Sales**

**Start**
- **Design Goals**
- **Design Input**
- **Design Output**
- **Launch Decision**
- **Launch**
- **Post Launch Review**

- **This is promising. Find out more and get back to us**
- **This is what we need**
- **This is what we want to make. The best concept has been identified and is feasible**
- **Development is finished. Specifications have been met**
- **We can make it. We are ready to sell**
- **We sell the product**
- **Lessons learnt**

Additional checkpoints may be agreed on if needed.
Software Product Deployment

- Start: Software product is validated (Design Output)

- Actions to launch software as global products
  - Produce CD /DVD, licenses, documentation
  - Continue external evaluations (routine-like conditions)
  - Localize software and documentation
  - Set-up of maintenance environment
Production Process for Software Products
Quality Checks in CD Production

DO
- Evaluation CD
- Copy CDs
- Series Master for Manufacturing
- Quality Control of Copies
- Series Master for Quality Control

LD
- External Evaluation
- CD Production
- IPC
- Series Production CDs
- Production Sample CD
- R&D Final Product Quality Control
- Product on Stock

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Software Localization

Challenges

• Software, On-line Help, and Documentation in target languages
• Localization of software including 3rd party components
• Safety of Localized Products
Safety of Localized Software

- Validation of software functionality.
- Validation of support material.

The validation of localized software requires the following checks:
- Installation for target language.
- Form checks (e.g. size checks for complete visibility of string labels and edit fields on the GUI and in reports).
- Presentations of data formats (e.g. date, decimal points, etc.).
- Linguistic correctness (proper translation and usage of terms).
- Functional correctness (e.g. user selected commands fulfill their intended use).
- Completeness of translation (e.g. no user interface messages in master language).
Software Localization Activities

1. Master Language Software Release
2. Create Strings
   - Glossary
   - Translatable Strings
3. Translation
   - Translatable Strings
   - Target Language Strings
4. S/W Build
   - Localized S/W
5. Test Plan, Test Design
6. V&V localized Software
7. V&V Passed?
   - Yes → Release
   - No
8. Master Language
   - Support Materials
9. Realize localized S/W
   - Translation
   - Online Help
   - Localized S/W with support Material
cobas IT Product Portfolio
one brand for professional IVD IT solutions

cobas IT 1000 solution
Work Area Manager for hospital point of care

cobas IT 3000 solution
Work Area Manager for central laboratory (e.g. PSM)

cobas IT 5000 solution
Laboratory Information System (launch in limited countries)