

Agile PLM Accelerator for Life Sciences Manufacturers



Pre-Configured for Rapid Implementation



Pre-Configured for Industry Best Practices

Manufacturers of medical devices & pharmaceuticals must comply with rigorously enforced standards. Frequently changing government directives require changes in product classifications, identifiers and other variables reflected in the workflow process.

Knowledge of Agile PLM is simply not enough – your implementation partner needs to understand industry requirements.

With our extensive industry understanding and robust solutions, we deliver a differentiated customer experience at every step of the customer life cycle.

Designed for all sizes of Life Science companies, our Agile PLM Life Sciences Accelerator solution, based on Oracle's Agile Product Suite comprises:

- Pre-configured workflows
- Data models
- Test scripts
- Optional pre-configured integration to Oracle E-Business Suite

Prepared with a 'Straw Man' configuration, our best practices assure faster implementations and improved processes, all at a much better price.

Accelerated Benefits

- Reduction in development and process discovery time
- Reduced need for dedicated or full time customer resources
- Immediate execution of best practice validation techniques
- Immediate implementation of PC/PQ best practices engineered and configurable to how you do business
- Reduced implementation schedules

You Have Our Support

Support is provided for the identified business processes. Examples:

- Engineering Change Order
- Process Item Master and BOM Management
- Part Numbering

Distinguished Features

Our Agile PLM Accelerator for Life Sciences can be used with the Agile FDA Validation Protocol Package (written by USDM) for handling:

- Installation Qualification (IQ)
- Operation Qualification (OQ)
- Performance Qualification (PQ)

The Accelerator is engineered for compliance with 21 CFR Part 11, which can result in decreased audit time and increased auditor confidence.

Accelerated implementation means we rapidly bring Agile Product Lifecycle Management (PLM) and Product Quality Management (PQM) solutions into production to ensure you achieve low-risk, high-impact, cost-effective implementation that directly addresses your business needs.

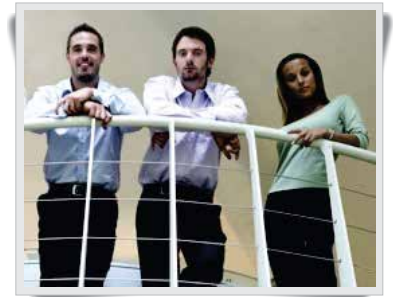
Structured Workshops

Business process discovery and requirements are completely tailored for Life Sciences. A structured workshop brings a relevant starting point for documenting key business processes, item template restructuring, revision control, and part number restructuring.

Implementation Deliverables tailored for Life Sciences

Examples:

- Item Masters
- File Attachments –Drawings, Artwork, Labels,
- MFG and MFG Part Numbers considering FDA & EU classification systems
- DHF –Design History File
- DMR –Design Master Record
- DHR –Device History Record



“KPIT’s Oracle Accelerate solution for Life Sciences combines our world-class product lifecycle management applications with KPIT’s expertise to deliver an affordable, rapidly implemented industry-focused solution.”

- Dan Scheib,

Vice President, Channels - North America Applications, Oracle

KPIT Oracle Practice provides Oracle and process-based expertise to Manufacturing, Automotive and Energy industries.

More than 2,000 Oracle professionals deliver a powerful combination of industry experience and Oracle knowledge in the following areas:

- E-Business Suite
- JD Edwards
- Agile PLM
- CRM On Demand
- Value Chain Planning
- Value Chain Execution
 - Oracle Configurator
 - Warehouse Management
 - Oracle Transportation Management
- Business Intelligence and Hyperion
- Fusion Middleware
- Global Services and Support

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