Life sciences company underwent acquisition and integration efforts that tripled the size of the company.

Disparate and disconnected product, quality and commercialization data across the enterprise.

Subject to large fines if it remained on the selling company’s IT systems for more than 18 months.

**Business imperatives:**
- Integrate newly formed organization
- Improve compliance and traceability
- Gain design efficiencies
- Prepare organization for growth

**Approach**

18 month program to implement foundational compliance capabilities, followed by collaboration and requirements management capabilities.

Program delivered with the implementation of an Oracle hybrid solution of Agile PLM, Innovation Management and Product Hub Cloud.

**Wave 1**
- Foundational FDA Compliance Capabilities
  - Quality management to enable management review, CAPA, audits (Agile 9)
  - Document management under change control (Agile 9)
  - Document access (PH Cloud)
  - Structured product data record with items/BOMs synchronized with production under change control (Agile 9, PH Cloud)
  - Integrations between Agile 9, PH, EBS

**Wave 2**
- Collaboration and Requirements Traceability Capabilities
  - CAD collaboration with Agile PLM EC and SolidWorks
  - Company-wide requirements management solution (IM)

**Results**

- Company is now a leader in Closed Loop Quality Management capability
- From 3 tools to manage CAPAs, Audits, and Product Non-Conformances to 1 global system for all
- Improved data accuracy with automatic synchronization of product data across multiple systems
- Elimination of redundant data entry between systems
- Full digital distribution of quality data
- Maximum reuse of design intellectual property
- Majority of users rate the layout and usability of the Agile interface as above average or exceptional