Auditdata
– Your Partner in Audiology Solutions

Real Ear AuditBase System Strato

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Your Partner in Audiology Solutions

My PLM ”Road map”

- 20 + years experience within medical device development, production, PLM and quality management (1988-)
- Agile PLM and QMS architect GN Otometrics (1999-2007)
- Agile PLM and QMS architect in Dako (2007-2011)
- Aras PLM, QMS architect and Quality manager in Auditdata (2011-)

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About Auditdata

- Established in 1992
- Development of audiology software and hardware
- Market leading position
- Strong competences
- 50+ employees in Denmark, Ukraine, Germany and the UK
- Organic growth last year at 40% expect similar growth rate in the next tree years
- Facing explosion in product complexity and compliance management

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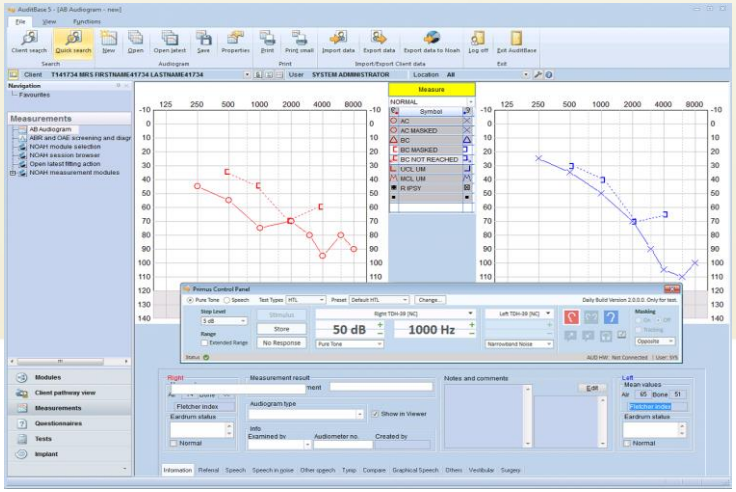
AuditBase

Public sector audiology solutions

- Client-server solution for electronic data management (Patient records)
- Patient Administration System (PAS) integration
- Comprehensive suite of add-on modules
- Installed base of 200+ clinics and 4,000+ daily users
- MDD Class 1



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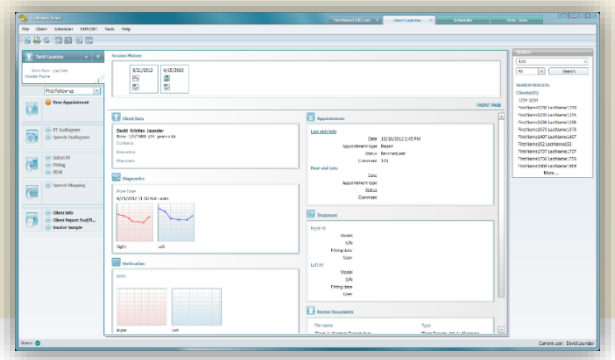
Strato

New generation office management system

- Client-server solution for electronic data management (Patient records)
- Online database in the cloud
- Microsoft Azure cloud platform (ISO 27001 certified)
- Not medical in EU but class 1 in US!



Powered by Windows Azure

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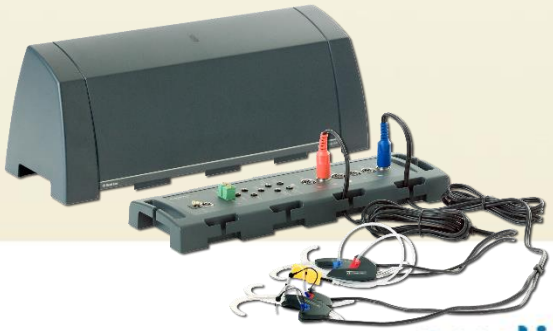
Primus

Audiological measurement solutions

- Audiometry -
- Real ear measurements
- Speech Mapping
- Hearing instrument testing
- Client Counselling – counselling support
- All in one software solution and modern hardware
- MDD Class 2a



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Certifications

- ISO 27001
- ISO 13485 Annex II
- MDD directive EC Certificate
- N3 certified (UK)
- NOAH 3 & 4 certified
- Microsoft Gold Certified Partner

N3

NHS
Connecting for Health

Noah 4

Microsoft
GOLD CERTIFIED
Partner

CE

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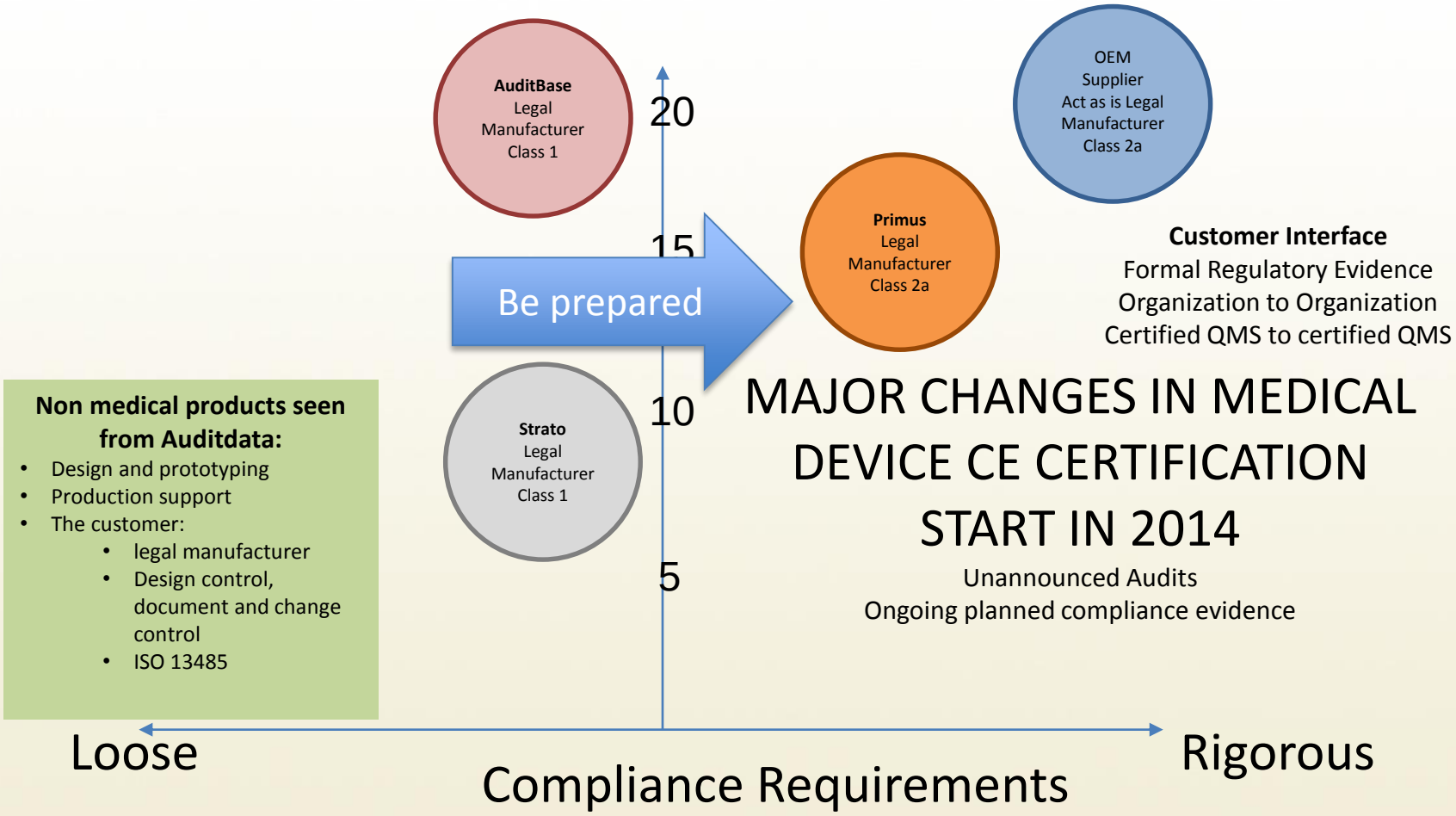
Our design complexity



Why PLM at Auditdata

A journey to fewer systems and greater consistency

“A place for everything and everything in it’s place”

- Multiple change and CAPA database(s) to assign numbering and report archiving
- Validation database to handle validation reports
- DHF, risk file and technical file on fileserver
- Design Change, change order and CAPA documentation on fileserver
- File server archive for quality management system
- File server archive for production work instruction
- DMR in Excel

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Why Aras PLM at Auditdata

- One Application - One UI
- Business Ready Application
  - Key drivers in Auditdata's selection were Aras's flexible platform, Minerva's track record in the medical device industry, and the speed of implementation for the total solution.
- Our choice to go with Aras and the Medical Device PLM was based on the comprehensive functionality, flexibility in the Aras product and total cost of ownership

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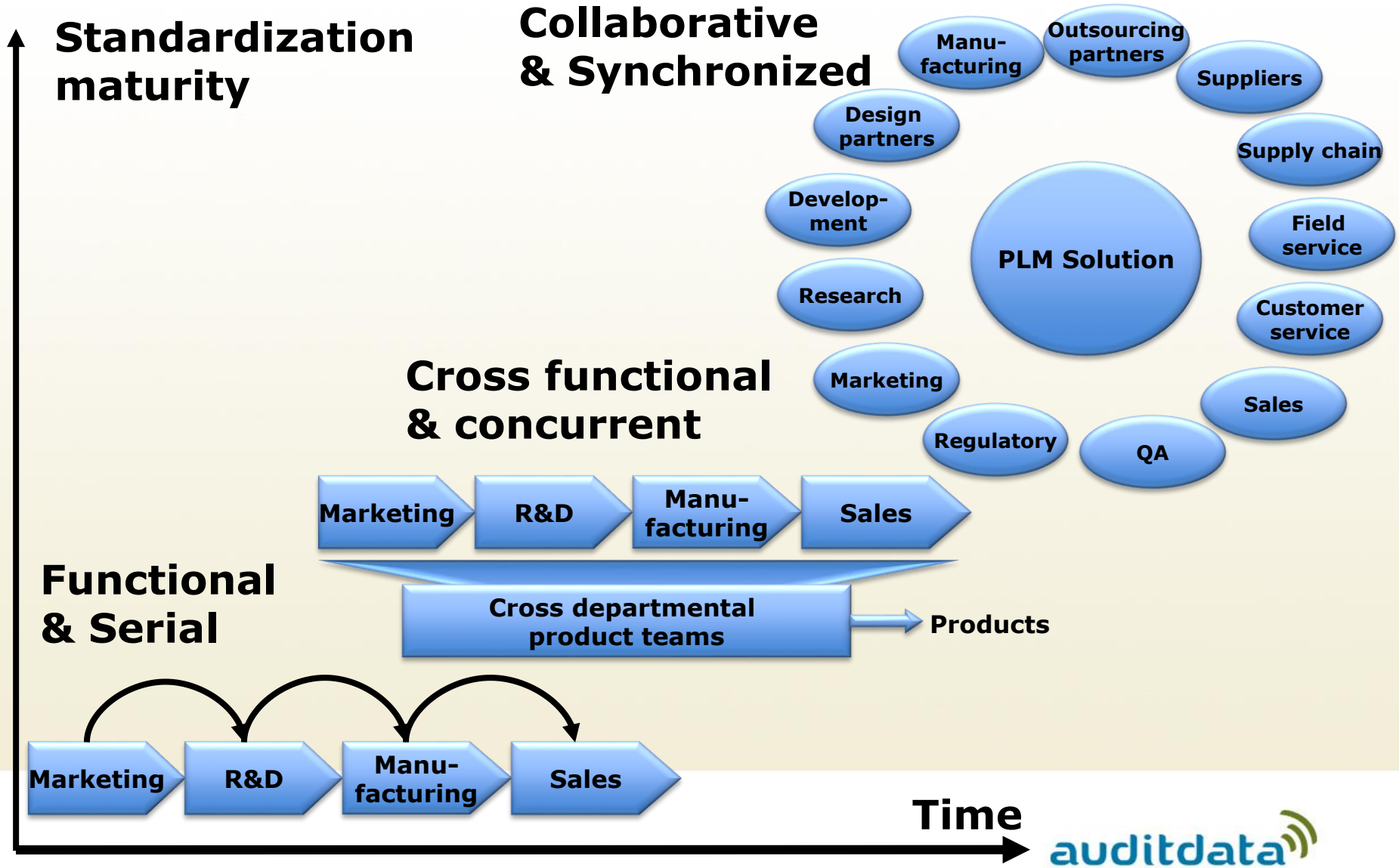
NABC – PLM System

NABC – PLM System	
Need	• Increase effectiveness of QMS to handle significant increase of Device Master Record and Design History File complexity and ensure high level of quality and agility. • Ensure Medical Device Products market and partner compliance
Approach	• Implement enterprise PLM solution to get a single solution to handle all product and quality process related data • Aras Innovator PLM solution – Open Source – Free + Subscription • 15 days of Consulting to implement a standard PLM solution
Benefit per Cost	• Multiple change requests execution per product • Reduce change request process complexity by ~50 % • Central Device Master Record for all stakeholders (including outsourced production) • Flexible regulatory delivery project & task assignments • FDA part 11 electronic signature compliance • Managing 200.000 files & 16.000 folders (growing)
Competition	• Existing file based QMS (strong limitation – Best practice not an option) • Oracle Agile PLM ($350.000 list price)

Why PLM? It Enabling us to accelerate!



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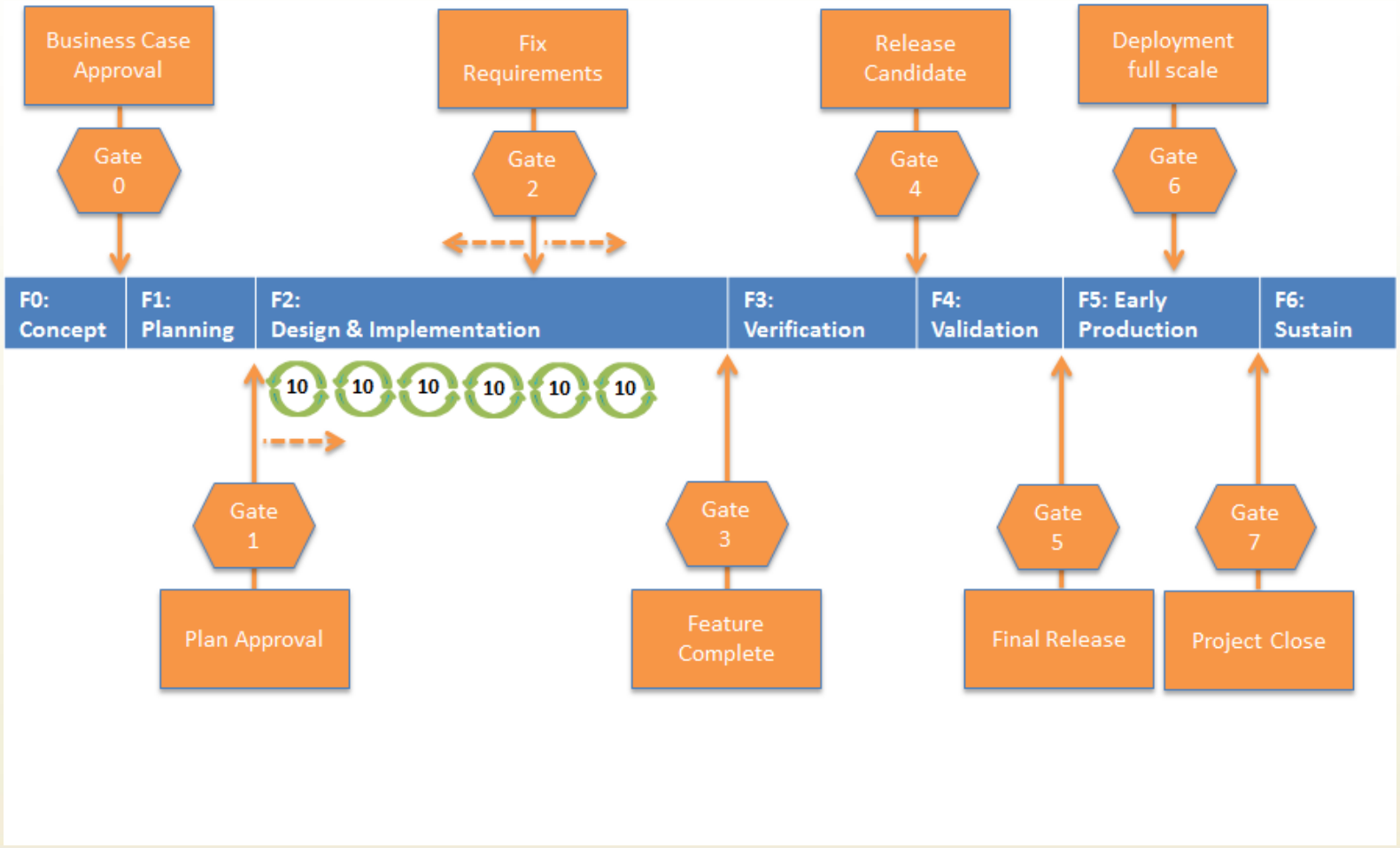
Development Process



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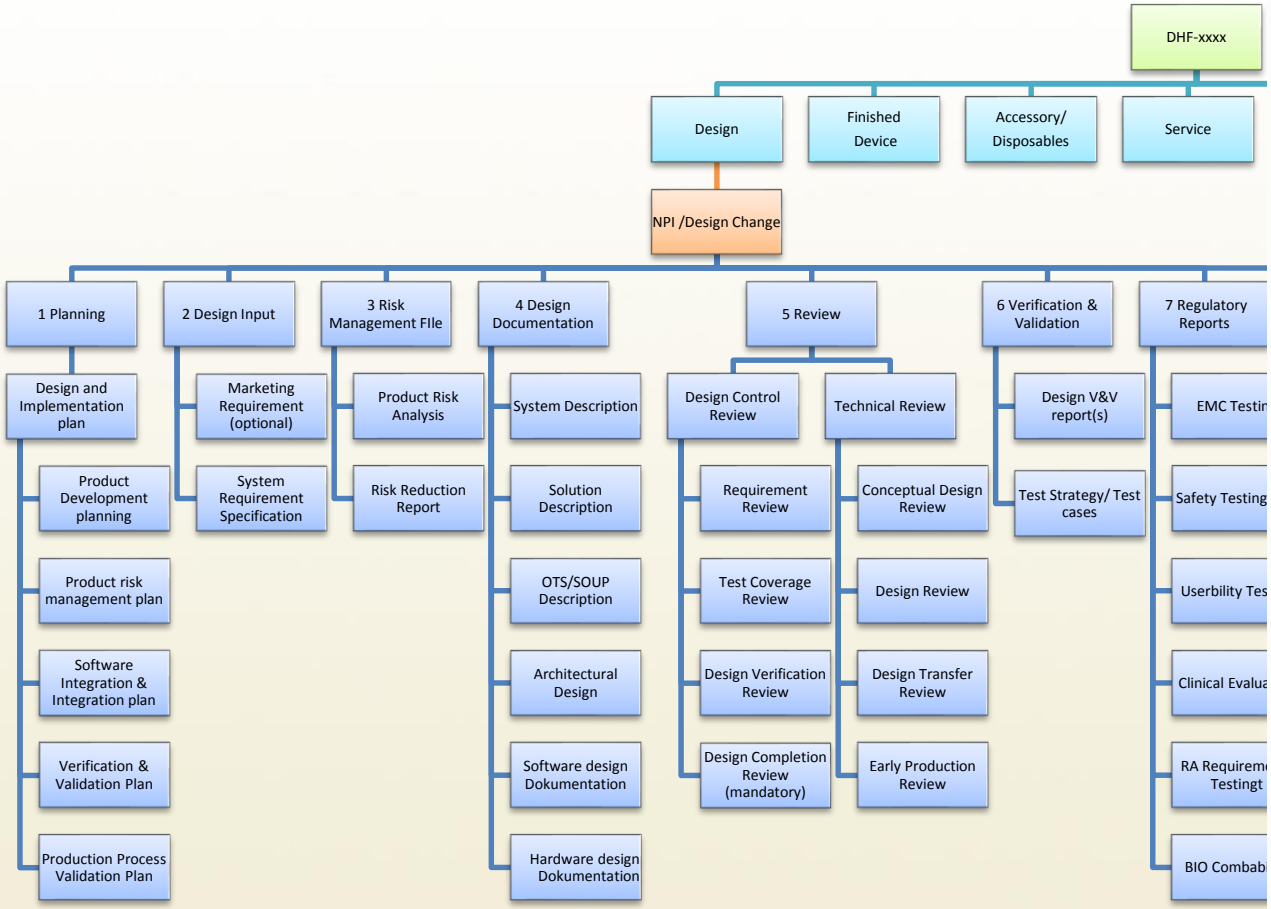
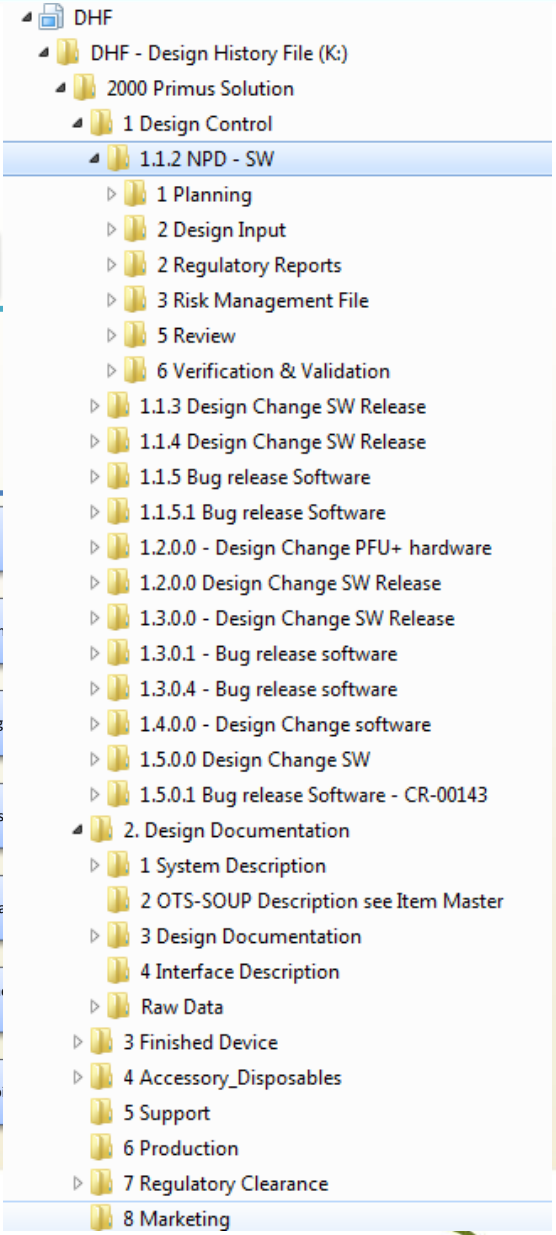
DHF/DMR/Technical file





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Current MedDev Situation

DHF

Making the document

Revising the document

Does this Impact other documents ???

Review and Signing the document

- What is the status, are we on time or ???
- what when other items is changed and impact other items and project
- How did it look 6 month ago and what have we changed
- How will you manage the product design details as a part of this with product structures, parts/components, changes etc..

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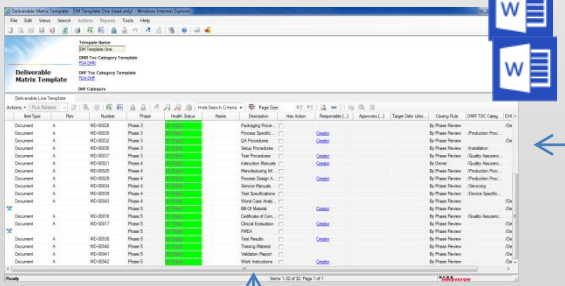
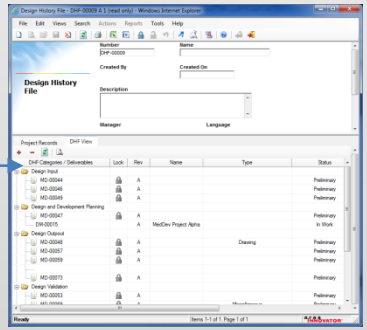
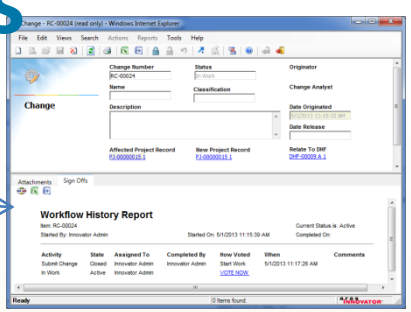
Medical Device DHF/DMR in Aras

Deliverable Matrix

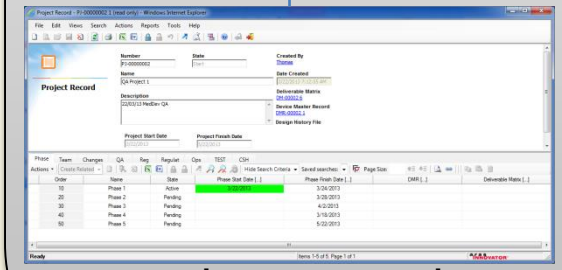




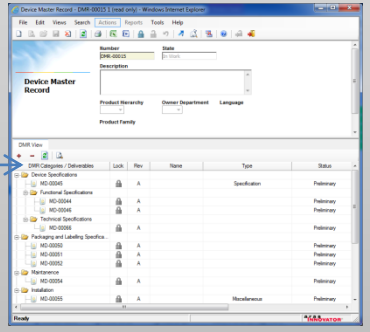
DHF



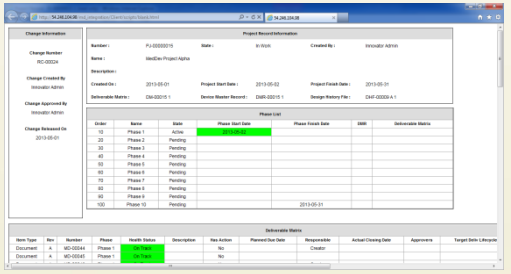
Gate Review



Project Record



DMR



Baseline / Reporting

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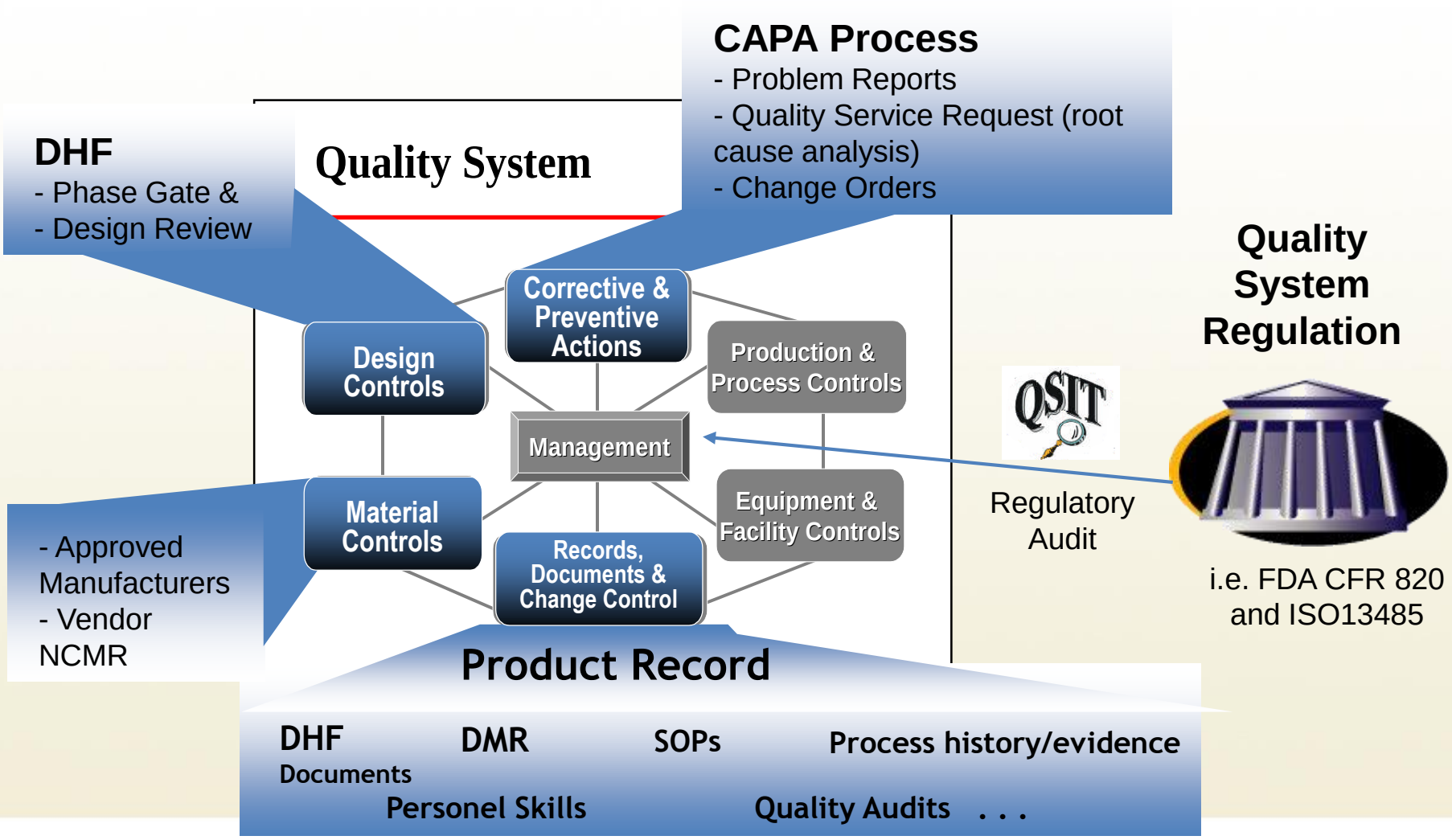
Enabling Regulatory Compliance with PLM



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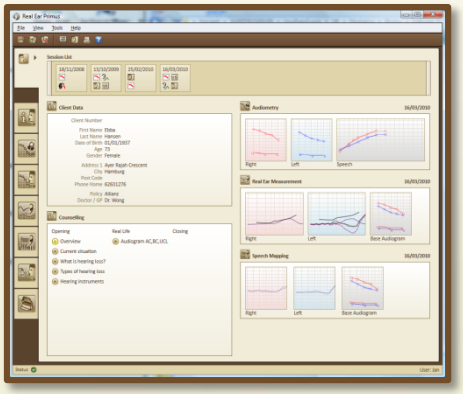
PLM implementation Status

- Expected GO-Live Q2-Q3-2014 (Aras 9.4):
  - Minerva MDD template (DHF project management)
  - Minerva electronics and high tech template (document, change control and workflow)
  - Minerva import module
  - Minerva permission manager
  - Office integration
  - “paperless” DHR and DMR
  - “paperless” Document control
  - “paperless” Change control



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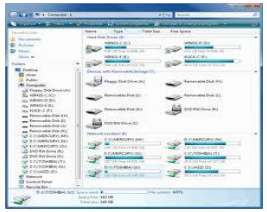
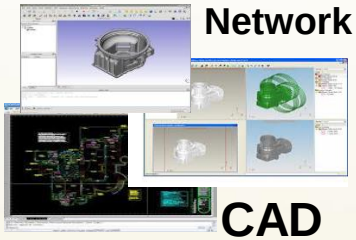
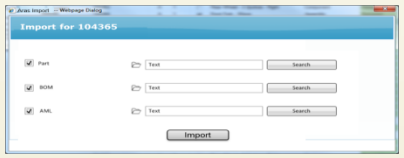
Medical Device PLM Overview

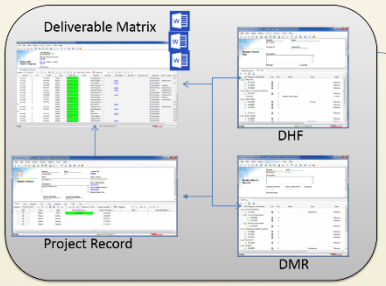


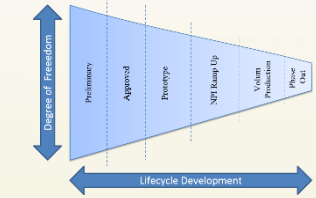
Network Drives

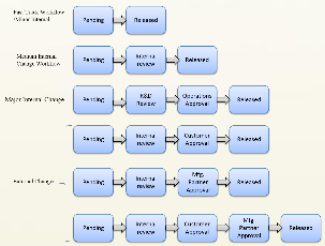


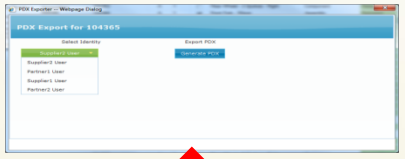
CAD











QAD

SAP

ORACLE

Microsoft Dynamics

XML

WPH

inerva Productivity Tools Office Connector

inerva Productivity Tools PDX Export

inerva Productivity Tools Import Tool

inerva Productivity Tools Permissions Manager

inerva Industry Solution Medical Device PLM

inerva Industry Solution Electronic & High Tech PLM

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Future in Aras

- Minerva CAPA – Corrective Action Preventive action
- Aras CE module (Rohs II compliance)
- Minerva NCR - Non conformity
- ITIL change order (ISO27001)
- SharePoint integration
- External manufacturing site on-line

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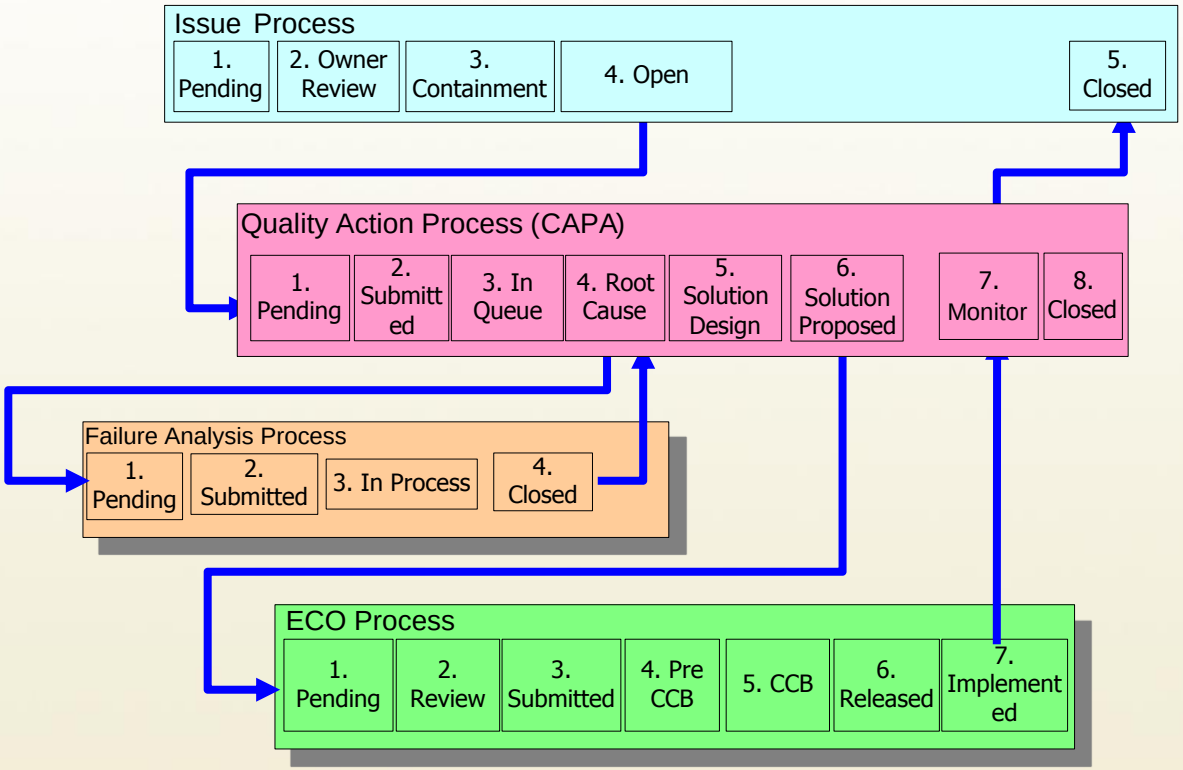
Minerva CAPA and issue process



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Questions & Answers