MES
生产执行系统

EBR
电子批记录系统

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Pain point and application scenarios

Building of New Production Facilities

Digital transformation Pharma 4.0

Data Integrity Issues

Migration of MES

Solution Pitch

NNIT helps to design a Pharma 4.0 manufacturing IT and automation architecture and to make the right decision with their MES investments to be ready for Pharma 4.0.

MES and Automation

Clients

- Biologics pharmaceutical company, Singapore
- Chemical API pharmaceutical company Singapore
- Medical device company, Singapore
- Vaccine manufacturing company, Singapore
- Service provider, Singapore
- Nutritional company, Singapore
- DCS vendor, Singapore
- Biologics pharmaceutical company, India

Services

- URS development
- Business case evaluation
- Implementation services:
  - Project charter / project initiation
  - Project Management
  - Stakeholder Management
- Validation Services:
  - Validation lifecycle management documentation
  - Test script development
  - Test execution
  - Project Quality Manager
  - Quality management
- Electronic Batch Record Management
- Recipe Management

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DeltaV DCS - Multiple Clients in Singapore

Clients

- Swiss Multi-National Bio-production facility
- Swiss-American MNC – E. coli and CHO facilities
- Swiss CMO Biologics Production Plant
- UK Vaccines Production Facility
- US Biotech Facility
- US Biologics Facility

Services

- Implementation support services:
  - Change hardware to from thick to thin client
  - Virtualisation
  - Project charter / project initiation
  - Integration and Shakedown
  - Data Migration
  - Project Management
- Validation Services:
  - Validation lifecycle management documentation
  - Test script development
  - Test execution
  - Project Quality Manager
  - Quality management / Validation

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Siemens (PCS7 DCS and XFP MES)

PCS7 DCS

- Cooperated with Siemens since 2013

- Act as Project Quality Manager on behalf of Siemens

- Author project quality documentation

- Train Siemens and client personnel on project documentation requirements

- Propose risk-based solutions for project change assessment

- Coordinate project meeting

XFP MES

- Appointed by Client since 2014

- Perform MES validation activities including authoring validation plan, protocols, report and other validation deliverables

- Localize site requirements against global requirements

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POMSnet MES
Implementations and Support for US Biologics / API MNC (multi-site)

Lead competency training to Manufacturing and Quality personnel	Manage Access Management service	Perform Master Data configuration
Author recipe	Perform on-site troubleshooting	Deliver Go-Live Hypercare support

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Syncade MES - Multiple Clients in Singapore

Clients

- Biologics pharmaceutical company, Singapore

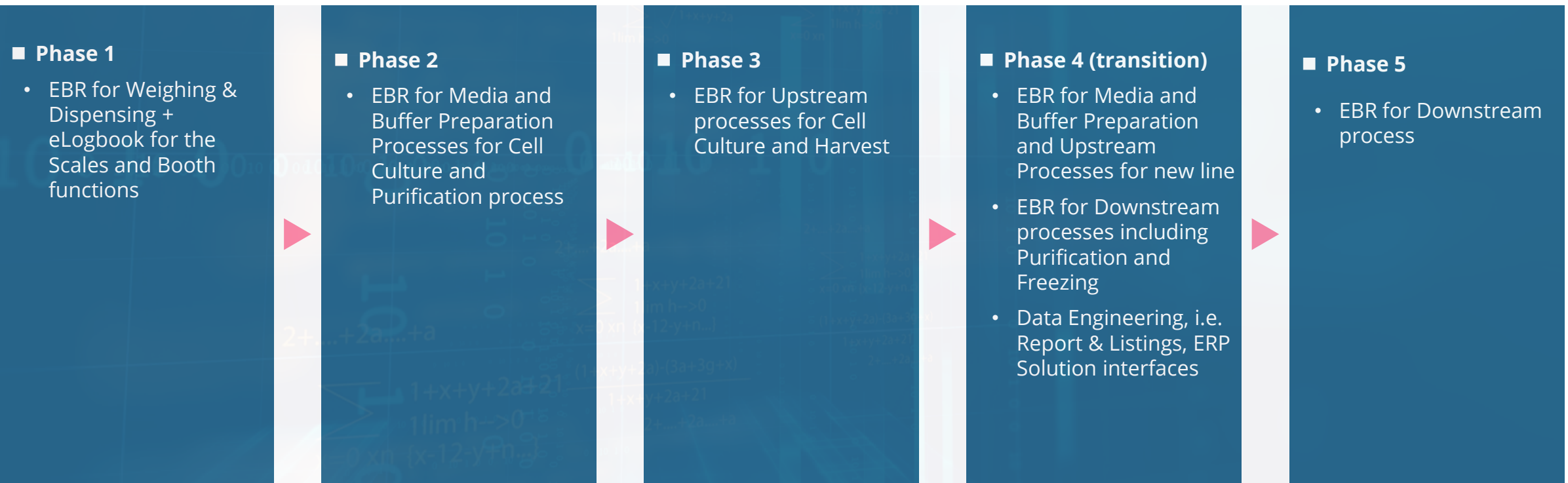- Biologics pharmaceutical company, India

Services

- URS development

- Business case evaluation

- Implementation services:
  - Project charter / project initiation
  - Project Management
  - Stakeholder Management
  - Multi Site implementation Strategy and Plan

- Validation Services:
  - Validation lifecycle management documentation
  - Test script development
  - Test execution
  - Project Quality Manager
  - Quality management

- Electronic Batch Record Management

- Recipe Management

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MES - Syncade MES Implementation
Biologics pharmaceutical company, Singapore
(Feb 2020 to present)

- **Deployment of** MES Syncade Technical Expert and MES Sycade Teachnical Lead to provide technical support and system quality to Novartis SGBO MES Syncade implementation.

■ **Phase 1**
- EBR for Weighing & Dispensing + eLogbook for the Scales and Booth functions

■ **Phase 2**
- EBR for Media and Buffer Preparation Processes for Cell Culture and Purification process

■ **Phase 3**
- EBR for Upstream processes for Cell Culture and Harvest

■ **Phase 4 (transition)**
- EBR for Media and Buffer Preparation and Upstream Processes for new line
- EBR for Downstream processes including Purification and Freezing
- Data Engineering, i.e. Report & Listings, ERP Solution interfaces

■ **Phase 5**
- EBR for Downstream process

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WERUM PAS-X MES Experience:
Implementation for Biologics Production (Japanese MNC)

Implementation of standard MES WERUM PAS-X 3.2

Suite 1: New implementation

Suite 2: Replaces existing MES installation

Professional Services delivered

Project Manager: PM with Technical Capabilities, oversee overall site MES implementation, localize site requirements against global requirements

Project Validation Lead: Perform MES validation activities including authoring validation plan, protocols, report and other validation deliverables

Integration Lead: Qualify Standard Automation Integration Layer (SAIL)

PAS-X MBR Designer & Technical Support: Perform MBR design / recipe authoring and system configuration

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MODA Platform for Bioprocess and CGT Manufacturing

MODA-EM environmental monitoring:

- Completed: Quality oversight on MODA-EM implementation
- Ongoing: Support for MODA-EM routine operation

MODA-ES Electronic logbook:

- Completed: Phase 1 - qualification
- Ongoing: Phase 2 - process building and qualification

MODA-ES Electronic batch record:

- Ongoing: eBR recipe building and qualification

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Tulip Frontline Operations Platform for CMO and solids packaging line

Decommissioned customised ERP/MES solution

Developed App and qualified them for processes including:

- In-Process Control Sample
- Visual inspection
- Process time management
- Line clearance and cleaning
- GMP review and release

Integrated App with ERP and Scales

Developed Dashboard for in process control sample

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Why NNIT?

Our Strengths

- Deep Understanding and Knowledge of Pharma
- Science and Risk Based approach
- NNIT enables clients to master the digital transformation in production and supply chain
- NNIT's methodology reduces implementation risks (scope, costs, wrong solution provider, excessive customization, organizational change)
- NNIT delivers e2e service.
- NNIT is vendor agnostic

Key Differentiators

- Thought leadership
- Dedicated to Life Sciences Industry
- Turnkey services (end-to-end)
- NNIT methodology
- NNIT takes ownership
- Take a **big picture approach**, and all projects and assignments are delivered with **a program to ensure quality** of delivery

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