Laboratory Data Management Systems

Colin Taft, J&L LES project lead
Eddie Ryan, Director, Systematic I.S. Strategies
Introductions

- Eddie Ryan, Systematic I.S. Strategies Ltd
  - BE, MEngSc, PMP
  - 17 years experience in manufacturing systems
  - 1995 – 2004
    - Systems integrators (manufacturing focus)
    - Past Roles: Programmer/Analyst, PM, Consultant, Manager, Director
    - Application Areas: Laboratory, MES, & plant/enterprise integration
    - Industries: Chemicals, Food & Beverage, Clinical, Pharmaceuticals
    - Projects: Ireland, USA, Europe, Middle East
  - 2005-2013
    - Systematic I.S. Strategies Ltd.
    - Independent Project Management, dedicated to regulated Life Sciences
    - Information systems strategy, selection, & program/project management
Introductions

• Colin Taft, Senior Manager, Pharma Lab Systems
  – BSc, MSc, PhD
  – 10 years experience with J&J
    ❖ 2003 – 2011
      ❖ Microbiology lead for new sterile API manufacturing facility start-up and qualification
      ❖ Various QC manager roles – Microbiology; Small molecule release; Large molecule release labs
    ❖ 2011-2013
      ❖ Business owner for a number of lab systems platforms (LES, Empower and SDMS) for our commercial manufacturing network of labs with Pharma sector of J&J (Janssen Supply Chain) – 22 sites
      ❖ Focus on standardisation and system deployment as global platforms
Introductions

Areas where a focus on good practice (GAMP) & computer systems regulations is required.
Introductions

Best In Class Systems
(integrated, by business function)

Laboratory Data Management
- LIMS (samples, methods, results)
- ELN (procedures, preparations)
- CDS/NDS (HPLC/GC control & data)
- Bench equipment (data acquisition)
- Data integration to plant & enterprise
- Manufacturing Intelligence

MES = Manufacturing Execution System
EBRS = Electronic Batch Record System
LIMS = Laboratory Information Management System
ELN = Electronic Laboratory Notebook
CDS = Chromatography Data System (or Network Data System)
SCADA = Supervisory Control And Data Acquisition
DCS = Distributed Control System
EAM = Enterprise Asset Management
CMS = Calibration Management System
FMS = Facilities Management System
ECMS = Electronic Content Management System
EDMS = Electronic Document Management System
EQMS = Electronic Quality Management System
LMS = Learning Management System
PPS = Production Planning System
WMS = Warehouse Management System
MRP = Material Requirements Planning
ERP = Enterprise Resource Planning
Bench = lab bench-top equipment proprietary software & firmware

(www.sysiss.com) Best In Class systems map (see Glossary for systems abbreviations)
Current trends/challenges

From a project management perspective, the same general themes/challenges concerning good practice and compliance are evident in the laboratory, but focused on lab business processes and data. Example current themes are:

1. The cost of compliance in the lab environment
   • Is GAMP5 driving the cost of compliance down with respect to lab data management systems?

2. Leveraging lab data management suppliers
   • Have lab data management systems really matured in terms of meeting business & regulatory requirements (LIMS, ELN, CDS/NDS, SDMS)
   • Can laboratory systems ever be fully Off The Shelf - laboratory data structures are deep and complex & often require customization (GAMP category 4-5)?

3. The risks associated with the use of automated data manipulation tools
   • Are configuration management, data migration, & automated testing tools “safe” to use?

4. Does Excel still have a justifiable role in laboratory data management?

5. Compliance and verification challenges of integrating with lab data systems
   • Lab equipment, HPLC/GC, production/warehouse, QA systems, middleware or custom integration?

6. Local versus corporate roll out of lab data management systems
   • Local autonomy versus global templates, compliance risks, fitness for use risks?
J&J Target System Landscape (Large Site – High Automation)

ISA S95

Level 4

“Recipe Data Warehouse”

Level 3

ERP

MES

LIMS

LES

Level 2

PIMS

PCS

CDS

Level 1/0

Lab Instruments

Process Instruments

Automated Interface (Labs)

SDMS

Spec Mgt

ISA S95 Levels:

- ISA S95 Level 4
- ISA S95 Level 3
- ISA S95 Level 2
- ISA S95 Level 1/0

Quality Systems:

Trackwise, DocSpace, Compliance Wire

CDS: Chromatography Data Software
ELN: Electronic Laboratory Notebook
ERP: Enterprise Resource Planning
LES: Laboratory Execution System
LIMS: Laboratory Information Management System
MES: Manufacturing Execution System
PCS: Process Control System
PIMS: Production Information Management System
J&J Current Typical Lab Systems Interfaces

SAP

LIMS

Specifications

Doc Management

Consumables / Reagents

SOPs/ WI’s / TM’s

Raw data forms; Logbooks; Instrument reports

Analytical test pack Review & transcribe results

Empower

Instruments

Raw data files

SDMS

Network back-up

Manual back-up

Manual Interface

SAP PM

Maximo
J&J Integrated Lab Data Management Platform with LES (target)

Sample planning & scheduling
Sample info & test limits to LES
Final batch disposition to SAP
Generate CoA

LIMS

Method Execution
Instrument data capture
Review by exception
Final results to LIMS

LES

Instrumentation / Reagents

Direct Interface – Level 1 instruments; Data parsing from reports Level 2 (non-chrom) instruments

SAP

SAP SDMS

Smart Spec

SAP PM/Maximo

Empower

Supervisor Layer

Analyst Layer
Current Trends/Challenges

Project Management perspective:

1. Cost of compliance in the lab environment
2. Leveraging lab data management suppliers
3. The risks associated with the use of vendor automated data manipulation tools
4. Does Excel still have a justifiable role in lab data management?
5. Compliance and verification challenges of integration with lab data systems
6. Local versus corporate roll out of lab data management systems

From the business perspective:

1. System integration (LIMS-Empower; LIMS-LES; LES-Empower) & vendor support of same
2. Scalable solutions – vendors set up to support Enterprise deployments
3. Master data set-up in separate systems – mapping for integration
4. Data analytics and reporting
   - Visualisation of data for analysts
   - Data in context
5. Mobile solutions
6. Integration of external vendors / contract labs – security issues
7. Cloud based applications
Objectives

Round table discussion:

• The themes & challenges are suggested discussion topics for the round table session.

• Any other topics of interest welcomed

• Objective is to gain consensus on what the current challenges are and how we can address them