

IT Systems Strategic Planning  
Systems Development Evolution for the Biopharma Industry:  
A Blueprint For Implementation  
BSMA Conference  
Nov 8, 2011

# Typical IT Systems Strategic Planning: Objective & Strategy

## Objective:

**Establish IT Systems Strategic Plan & Roadmap that Addresses Business Needs for:**

- **Data Management** (electronic data capture and use)
  - Enabling business decisions and support business processes
  - Collecting/sharing /analyzing/trending data efficiently
  - Aligning data- single source of data truth (example reg filing vs MES vs ERP vs LIMS)
- **Functionality**
- **Architecture & Integration**
- **Infrastructure**

## IT Systems Strategy

- **Identify Desired Systems Functionality**
- **Identify Business Process Gaps**
- **Identify IT Systems that Provide Desired Functionality**
- **Establish Roadmap to implement/maintain those systems/functionality**
- **Establish Robust Process for IT Systems Project Proposal Assessment & Prioritization**
- **Establish a cross-functional Advisory board to review and guide the process**
- **Guiding Principles for more efficient implementation**
  - Use/leverage existing systems where appropriate
  - Avoid Customization—Use Commercial Off the Shelf Applications & Adjust Business Process as appropriate

## Strategic Planning—FAQs (Frequently Asked Questions)

- What is the strategic plan objectives?
- What is the desired future state system functionality?
- What are the current systems?
- What are the current issues/gaps/unmet needs?
- What are the desired system changes?
- What are the desired business process changes?
- What is process for proposing desired system changes & aligning with budget/authorization?
- What are the roles/responsibilities (IT, QA, Enterprise Apps, Advisory Board, Sr Mgmt)?
- What is the decision making process for system projects?

# Recommended Process to Establish IT Systems Roadmap

## Information Gathering:

- Document Information/Data Desired to be Captured
- Document Business Processes Associated with Data Capture & Use
- Document Future State IT Systems Required to Achieve Desired Functionality

## Assessment:

- Assess Current IT Systems Against Required Future State Systems
- Assess Current Systems for Issues, GAPS, Unmet Needs & Risks
- Identify System Changes /New Systems Required to Achieve Future State Functionality
- Assess Business Process Maps for Accuracy & Completeness
- Prepare Proposal that defines all required changes

## Prioritization:

- Review & Prioritize PI Project Proposals with Advisory Board

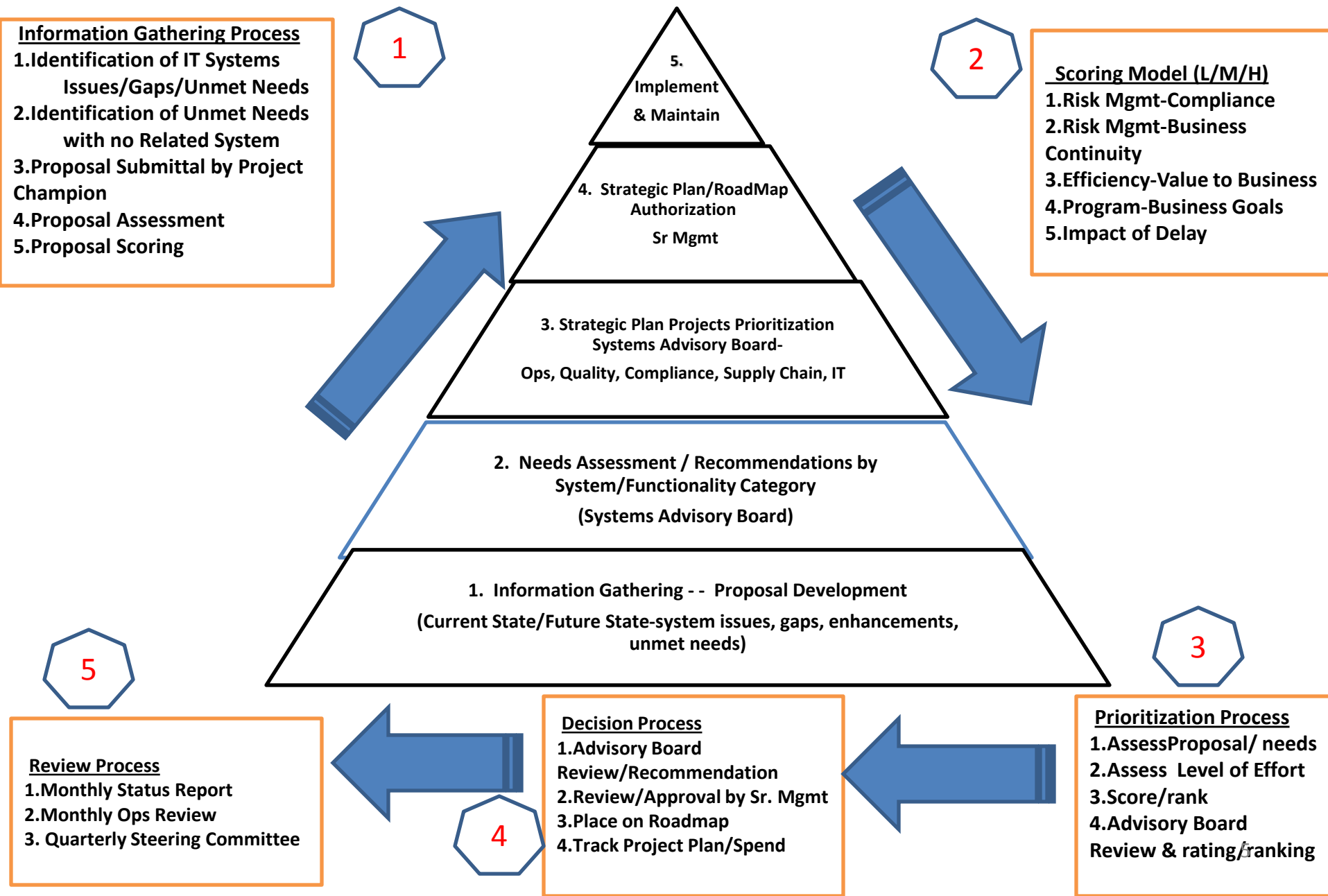
## Approval:

- Review/Approval of Advisory Board Project Prioritizations by Sr Mgmt
- Document Prioritization & Timeline on IT Systems Roadmap

## Implement & Maintain

- ROADMAP COMPLETED—Implement per Prioritized Schedule & Maintain

# Strategic Plan/Roadmap Development & Decision Process



# Typical Functionality Needs Assessment for IT Systems

Functionality needs-future view	Current system	GAPS	Future State
<b>1.ERP (multi-sites)-Supply Chain</b>			
1.1 planning , scheduling, forecasting			
1.2 purchasing, inventory mgmt, distribution			
1.3 Serialization			
<b>2.Content Management</b>			
2.1 GMP Documents			
2.2 non-GMP Documents			
2.3 Engineering Docs & Drawings			
2.4 Validation Docs/Records			
2.5 History Records (paper & electronic)			
2.6 Training Materials			
2.7 Log Books & Notebooks			
2.8 Collaboration			
<b>3.Change Control (all content)</b>			
3.1e-Approvals			
3.2 draft review/comment/reconciliation			
3.3 version control/promote to effective			
<b>4. DATA</b>			
<b>4.1 Data Collection (electronic vs paper)</b>			
<b>4.2 Data use, analysis &amp; processing</b> (query, reporting ,dashboard, analytics)			
<b>4.3 Data Management</b> -change impact assessment & control tied to central source of truth (reg filing)			
<b>4.4 Data-Batch Records</b>			
4.4.1 Master Record –create& maintain			
4.4.2 History Record— document, review, approve			
<b>4.5 Data-Lot Disposition</b> —review by exception			
<b>5.Equipment maintenance &amp; calibration-</b> (CMMS)			
<b>6.CAPA &amp; Discrepancy mgmt</b>			
<b>7.1 Lab Information</b> Mgmt System (LIMS)			
<b>7.2 Lab support systems</b> -CDS, plate management			
<b>8. Product Complaints</b> -documenting, tracking,			
<b>9.Compliance support</b>			
9.1.in progress audit information			
9.2 audit observations-response & commitment tracking			
9.3 external regulatory surveillance information			
9.4 product registration information			
9.5 compliance with regulatory submissions			
<b>9.6 Supplier Management</b>			
<b>10.Project Mgmt</b> —planning, scheduling, tracking			
<b>11.Manufacturing Automation Systems</b>			
<b>12. Learning Mgmt-Training System</b>			
<b>13.Validation</b> process automation support			

# Typical Current Systems—Gaps Assessment

<b>Current System</b>	<b>Scope</b>	<b>Integrations</b>	<b>Gaps</b>
Document Management			
Sharepoint			
CMMS			
Trackwise			
ERP			
<i>Query/Search Tool</i>			
<i>LIMS</i>			
Lab Systems: --Empower --SoftMaxPro --WinKQCL			
Manufacturing Automation			
Training/Learning Management System			
Compliance Applications			
Complaints			
ELN (E-Lab Notebook)			
Database Applications Quickbase/FMP			

# Typical Systems: Scope & Planned Changes

System	Scope	Planned Changes
1. Document Mgmt/ECM	QA Controlled docs, Eng Drawings, non-GMP Docs, Val Docs	
2. Trackwise	CAPA/Dev/DMS; Change Control	
3.CMMS	Cal & Maintenance Mgmt	
4. LIMS	Lab Data (EM, RM, Prod, Stability, Prc Dev)	
5. Training Mgmt-LMS	Training Requirements & Train Records	
6.Collaboration Tools	Provide more efficient review comments	
7.ERP/EBS	All ERP/EBS applications	
8.Query/Reporting Tools	Data query/reporting	
9.Empower	CDS for Lab chromatography data/calcs	
10.Soft Max Pro (SMP)	CDS for Lab Plate Reader data/calcs	
11.MES	System for mfg execution & e-BHR data	
12. Mfg Automation	Collect mfg process data	
13.Mfg Process	Captures mfg process capacity data	
14.ELN (Electronic lab Notebook)	Capture Process Dev Data	
15.Product Complaints	Capture/track product complaints	
16.Compliance Systems--Inspections in progress, Audit Commit Tracking	Support Compliance data needs	
17.Data Warehouse	Repository for data from ERP, LIMS, etc	
18.Validation Tools	Val doc processing; regression testing	
19.Data Capture and Analysis	Assess options to e-capture & analyze data	
20. Database applications	Used for Adhoc non-GMP data	
21.Facility Mgmt	Facilities Space Planning/Management	



# Typical Future State Systems—Changes Proposed

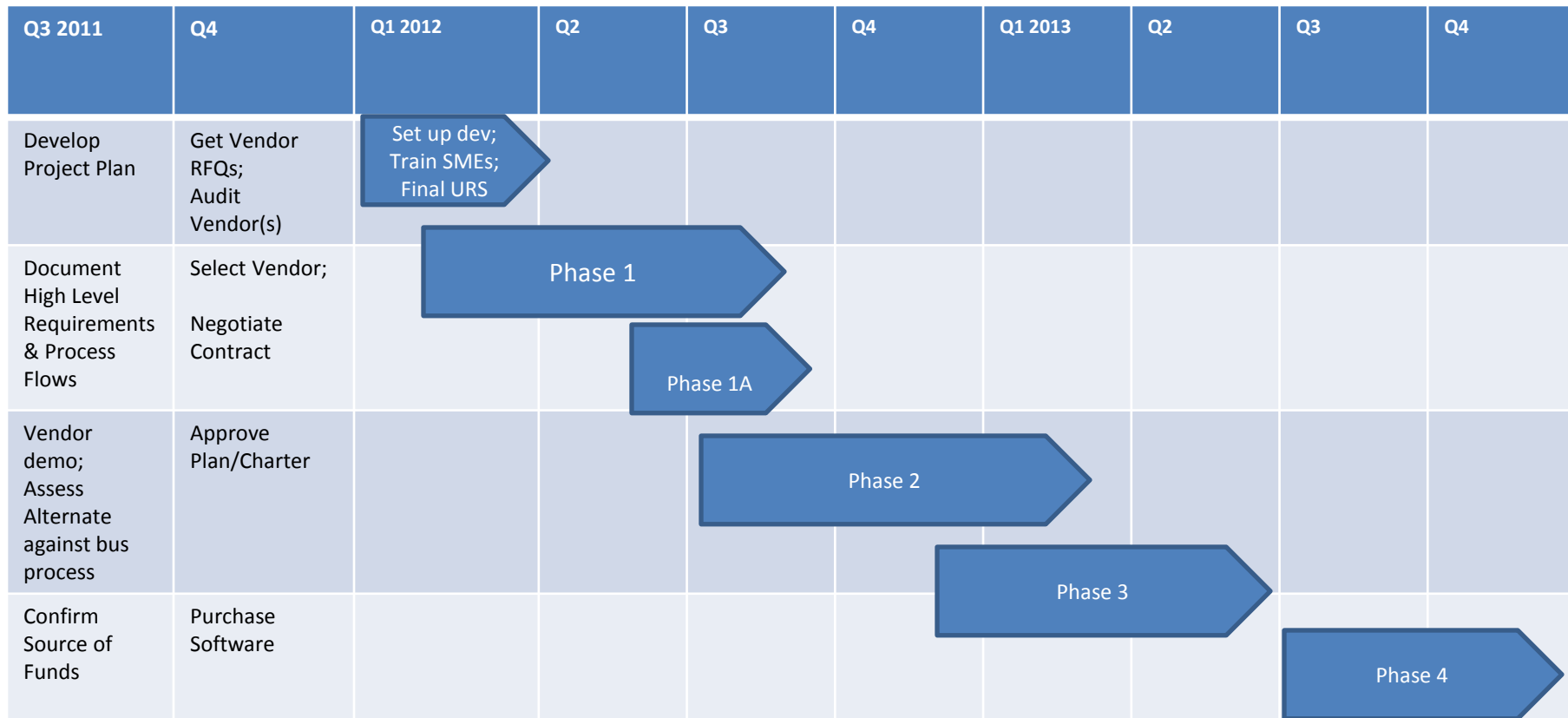
Future State	Scope	Integrations	Changes from Current System
<b>EDMS/ECM (Content Mgmt)</b>	Repository-all object types; workflows; collaboration; drafts		
<b>Collaboration tool</b>	Related to ECM tool		
<b>CMMS</b>	Calibration & Maintenance management System		
<b>Trackwise</b>	Discrepancies & CAPA Change Control; Complaints??		
<b>ERP</b>	Purchasing, inventory, distribution, scheduling, OPSM, MES		
<b>MES</b>	MES/e BHR for all mfg phases		
<b>Query/report Tools</b>	<i>Query/Report/Data Assessment</i>		
<b>LIMS</b>	QC Lab Test Data—EM, RM, IP/FP, Stability		
<b>Lab Systems: --Empower --SoftMaxPro</b>	-CDS for Chromatography Data -data processing for plate readers -endotoxin testing		
<b>Manufacturing Automation</b>	-production capacity analysis -equipment parameter monitor -bldg parameter monitoring -equipment/facility monitoring		
<b>Training /LMS System</b>	Training assignments and completion tracking		
<b>Compliance Applications</b>	Audit Information Response Tracking Registrations Vendor audits & address		
<b>Complaints</b>	Medical & non-medical product complaints		
<b>ELN (E-Lab Notebook)</b>	e-Process dev experiments		
<b>Database Apps</b>	Goals, projects,		

# Example Strategic Plan Roadmap-Prioritized System Projects-LRP

\*\*\*Refer to Chart--Systems & Planned Changes; Note: all projects will have unique project plan roadmap-see example

Project/System	2011				2012				2013				2014				2015				
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
1. EDMS/ECM					█					█											
2. Trackwise					█																
3.CMMS					█					█											
4. LIMS			█																		
5. Train Mgmt--LMS					█																
6.Collaboration Tools					█																
7.ERP/EBS					█						█										
8.Query/Report Tools)					█																
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13.Mfg Process					█																
14.ELN		█																			
15.Product Complaints					█																
16.Compliance Systems					█																
17.Data Warehouse			█																		
18.Validation Tools					█																
19.Data Capture/Analysis					█																
20. Infrastructure					█																

# Typical Example --Project Roadmap

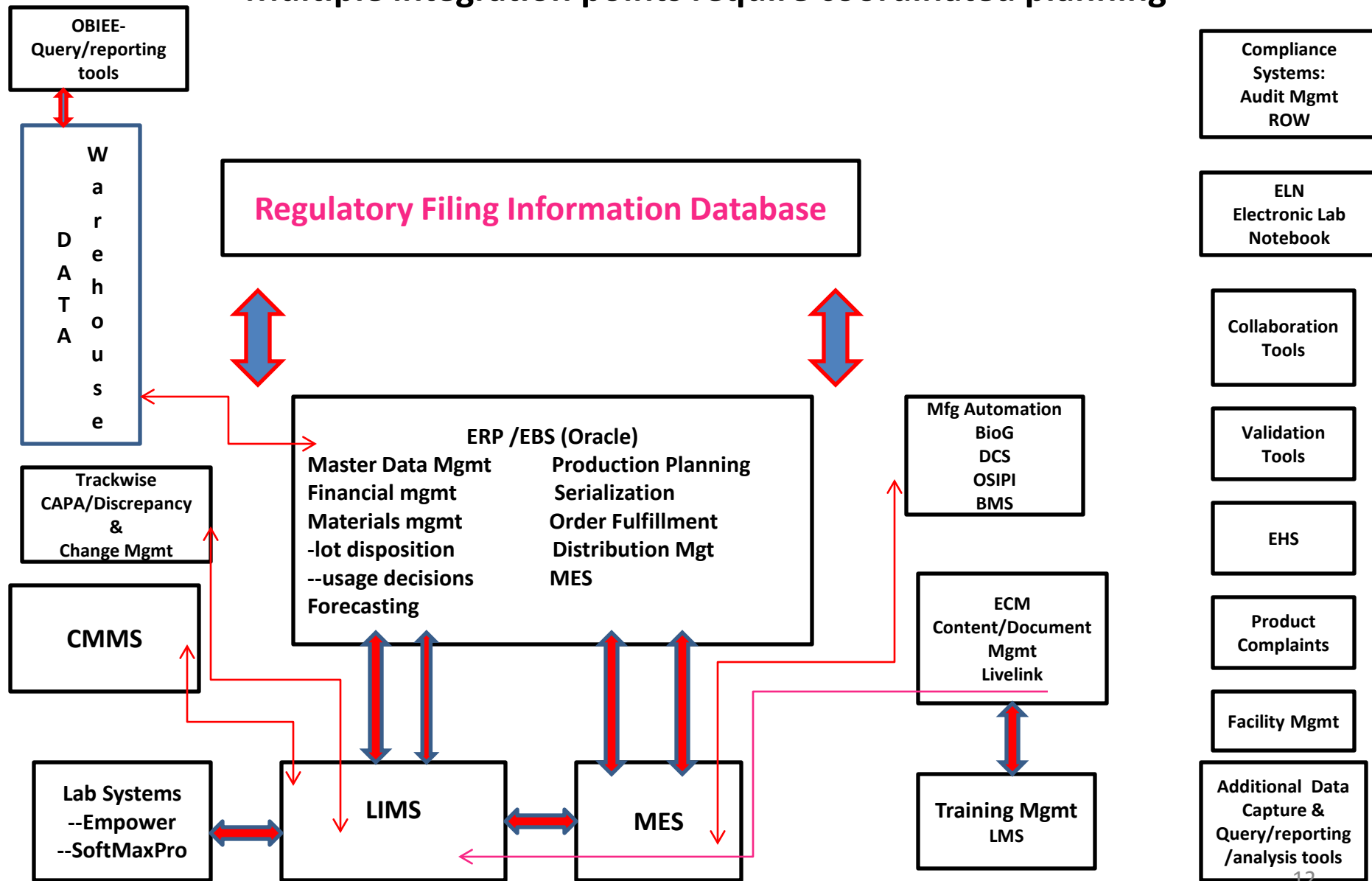


## Assumptions/Notes:

- Select/Implement Best COTS Application; assess business process/requirements against COTS functionality and adjust business process/requirements as appropriate
- SMEs to complete COTS training before developing application
- One system/application will serve all sites/functions
- Risk Based Validation methodology is used (leverage vendor val data)

# Future State Applications Architecture

Multiple integration points require coordinated planning



# Typical Project Implementation Issues

1. Project scope not always known or agreed
  - Requires additional unplanned resources, budget, and time
2. Indirectly impacted business users not involved
  - Additional resources required to fix issues that could have been avoided
  - User adoption and change management negatively effected
3. Internal resources not fully planned
4. Projects built off of non-updated URS documents
5. Quality not included in the project planning phase
  - New deliverables required in mid-project

# Key Project Implementation Guidelines

## 1. Identify the User Requirements in detail

- Assure requirements approved by Business Leaders & Maintained Current

## 2. Create an Implementation Plan that explains:

- The business driver for the project and deliverables
- Process charts and description of the Current and Future State
- Project Milestones--change development, testing, validation, deployment
- Change Impact and Assumptions/Dependencies

## 3. Gain agreement on the scope/Implementation Plan

- Assure the Implementation plan has agreement by all resource areas

## 4. Maintain Project Plan—resources, activities, responsibilities, timeline

- Assure adequate resources (Internal & External)
- Address impact to existing projects

## 5. Identify Project Oversight Members

- Assure Management Members from each functional area involved /impacted

## 6. Project Communications:

- Document/Publish the project meeting minutes, status and upcoming events
- Engage Users to review change impact and plan for change implementation