

LIMS DEPLOYMENT

Flat Pack Approach

WHITEPAPER



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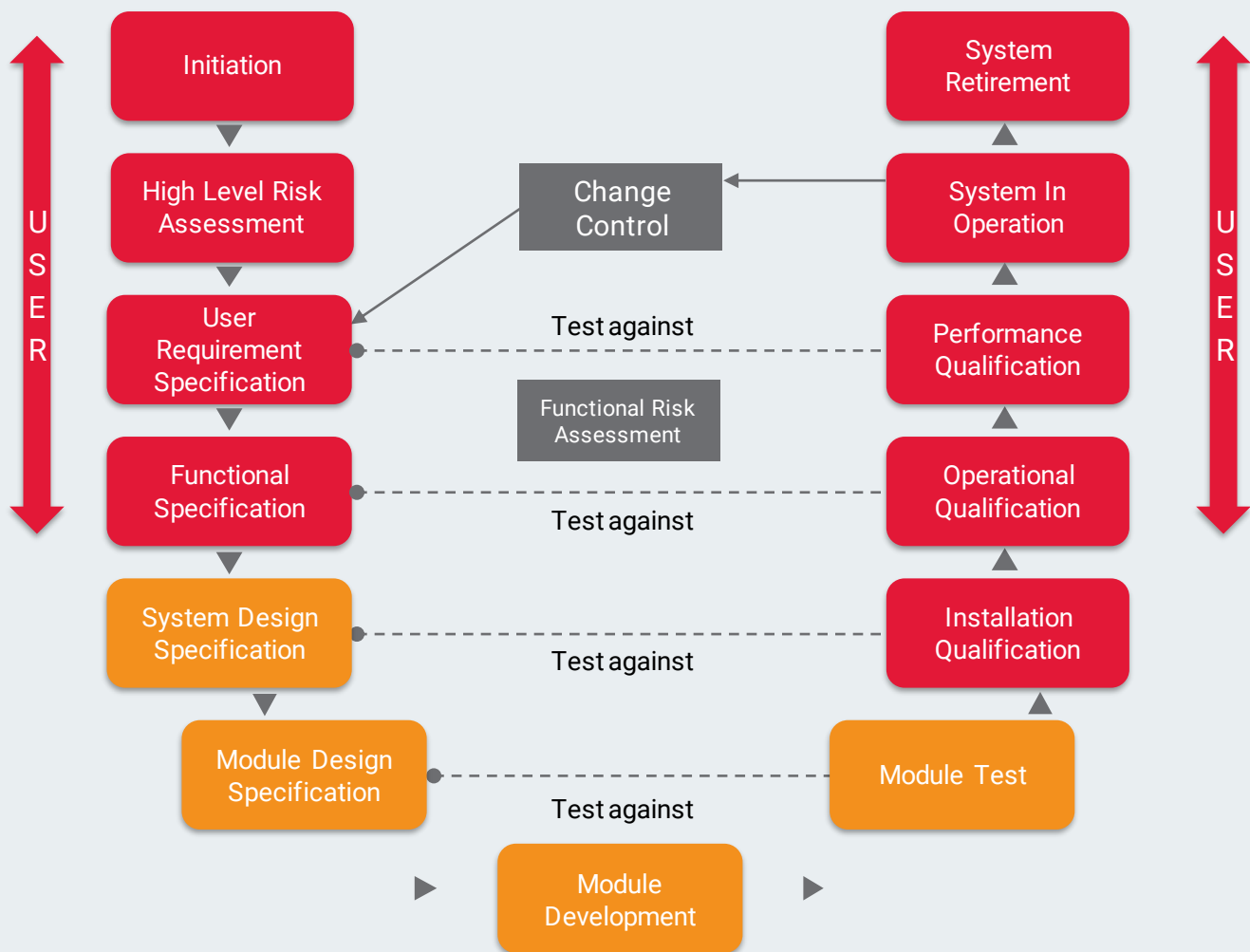
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Introduction

The concept of 'Flat-Pack' much used in furniture retail industry, the objective was how quickly customer on its own able to assemble a furniture. In today's fast changing world any service will be measured with Quality, Cost & benefits parameters. It's equally true for Laboratory Information Technology system. The Lab IT paradigm has been changing towards most efficient and cost effective, more compliant way of its Implementation and its usage be it a LIMS (Laboratory Information management system) or ELN (Electronics Lab Notebook) For a customer this constitute greater challenge in selection, Implementation and finally deploy across Labs or Sites. The Flat pack approach basically helps in identifying recurring deliverables, documenting learning, expediting certain validation process from Pilot implementation .

Post Implementation of Lab System, Customer will look for a faster, efficient way to deploy the product to various sites considering complexity in Validation and site acceptance it add additional cost and delay to the deployment. The standard Validation cycle for any pharmaceutical industry is represented below which shows various project phases and associated validation phase

General Lab system Validation flow



The above cycle is applicable for a standard Lab IT application Implementation as well as deployment activity for various sites. Generally when Lab is ready for deployment following question may come up.

Deployment assessment

Scenario: Lab IT system has been implemented for a pilot site and customer is planning to deploy similar configuration to other Labs or sites



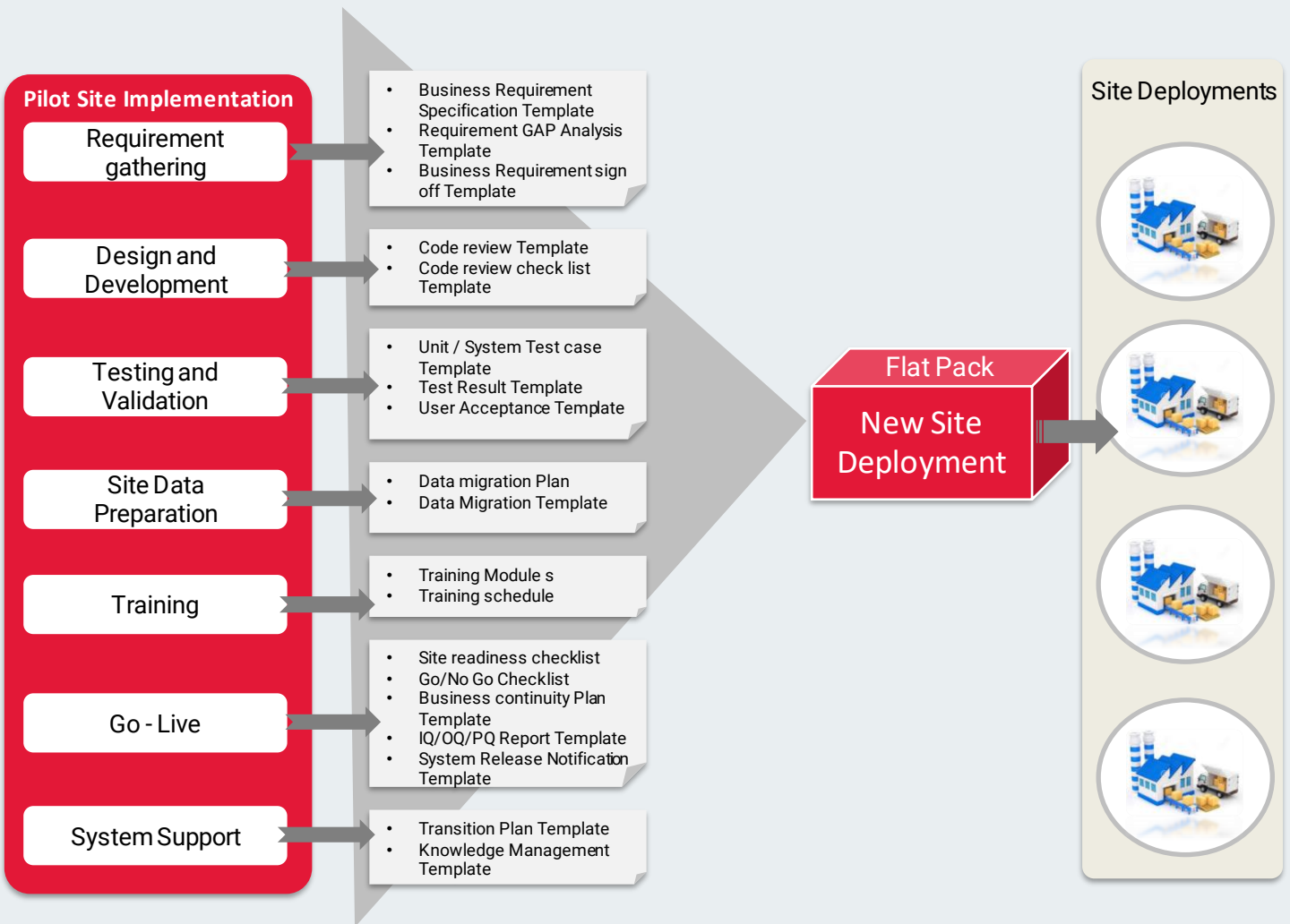
There are many task and learning that can be browed from Pilot implementation however to deploy the similar configuration customer will face following challenges

- Site specific configuration changes
- Adopting for Business change
- Data preparation
- Allocation of right resources
- Site training needs



Flat Pack approach

The scenario explains various stages we commonly encounter for a first or pilot site for Lab System Implementation. If organisation is having plan to rollout / Deploy the same configuration across other sites 'Flat Pack' approach will help in cut down cost & time. The Phase wise description has been given below



Requirement gathering

Post Validation Plan confirmation this is first phase of establishing IT system expectations. This phase is must for standard waterfall or agile methodologies for deployment there outcomes may come at different timelines .considering future sites for rollout its very important for project organization to have plan to generate information templates on what are similar requirements are applicable for future sites. What are they Must have & optional requirement e.g. Pilot site may want select a barcode interface for scanning sample labels in the Lab , future sites may have option to use barcode or keyboard. GAP analysis Template will help to detail down any variation in the process it also helps organisation to align sites based on GxP Standard Operating Procedures (SOP's)



Design & Development

Post requirement system designing process being, most of the enterprise level system may have approved architecture however configuration may differ slightly for future sites. The flat pack approach suggests creating a code review check list and Template to document this variation. This is important to considering future application support.



Testing and Validation

This is key phase as part of pilot as well as future deployment considering its impact on overall system acceptance. Testing of developed application is governed either by a site specific Test Plan or organisational plan. Number of Test cases will be drafted, get approved as part of this phase. The same test case can be utilized during the deployment to other sites. Test case Template can be generated for future deployment. Also as part of Validation Traceability Matrix template can be prepared



Site Data Preparation

Site specific Data may vary depending on Lab IT system site is planning to deploy e.g. for LIMS system Product information is important. As part of the Pilot implementation Migration plan and Static Data Template can be utilized for future deployments.



Training

Effective Training curriculum and content can be developed and reused during deployment. This will be helpful for producing site specific Training needs and plan.



Go-Live

This phase determine system is ready for production use and number of deliverable required to be prepared before system formal usage. Site specific readiness checklist template will help sites to determine if all prior activities are completed. Also help to raise new risk as part of review. For validated system Business continuity plan is one of the mandates. As specific for acceptance of validated system it should pass Installation/ Performance /operational Quantification tests. The process of testing remains the same for most of the future sites.



System Support

Post Go-live Support Transition and Knowledge management is part for better maintenance of the IT system. A generalise Support Transition Plan and checklist can be developed and used for future rollouts. May organisation maintain knowledge as part of articles/notes or technical write-ups. Some services can be utilized in flat pack approach.

Benefits

- Huge savings in overall deployment effort & cost.
- Faster deployment for sites.
- High reusability of the developed resources.
- Less dependent on individual and more driven by process approach.
- Huge reduction in validation efforts without compromising on IT Quality deliverables.



Author

Pavan Pasupulati is Principal Consultant with 21 years of experience in Lab Informatics with focus on digital transformation consulting, System Integration for analytical data management and advanced lab analytics.

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