Proven Strategies for Selecting a LIMS That Powers Your Digital Transformation

"He who stops being better,
stops being good - Oliver Cromwell

4th Industrial Revolution MOMI
Manufacturing Operations Management Institute
An Expert Division of ATS Global

1LIMS

Gerard Ipskamp – Senior Consultant

Knowledge

Business consultancy

- Manufacturing (IT)
- Quality management
- Asset Management
- Change management
- Awareness, feasibility, business cases
- MES/LIMS/MOM product selection
- Blueprint architecture and high-level roadmap

Profile description

Gerard has over 20 years experience in improving operational processes of industrial enterprises in Europe in a large variety of industry sectors. People and change management are equally important to processes and IT tools to achieve these improvements.

His experience ranges from the development of an application blueprint for the shop floor to an architectural design and the implementation of the production layer in relation with ERP (SAP) and the process automation layer.

Using the knowledge in many areas Gerard has experience in IT master plans, architectures and roadmaps. Combined with a strong sense for stakeholder management and change management this results in a focus for added value.

Gerard is involved and enthusiastic, pragmatic and focused. He inspires and motivates, and always remains focused on a balanced relation with the customer. Gerard is an excellent coach and instructor.

Roles

- Business consultant
- Trusted management advisor
- Architect
- Instructor
- Coach
- Facilitator workshops

Customers

- Oil and Gas companies
- Food and Beverage companies
- Chemical industry companies
- Pharmaceutical companies
- High-tech Electronics and Semiconductors companies
- R&D organizations
- Commercial and hospital Laboratories

Manufacturing Operations Management Institute

An ***Independent Expert Division*** of ATS Global

- Education services
  - MOMi is an authorised training provider for the MESA Global Education Program (GEP), and
  - our own catalogue of MOMi Manufacturing IT related education

  Education is most effective at start of a digital journey, transferring knowledge, giving structure and generate ideas.

- Business consultancy
  - Help to identify needs and value for digitalization projects in manufacturing
  - Manufacturing Maturity assessment
  - Identify requirements and help to select the right software solutions
  - Explore and support the related organisation change

  Business consultancy is based on proven practises, real-world experience and it is tailored to your specific needs.

Program

Effective Strategies for Choosing a LIMS That Drives Your Digital Transformation

- Transitioning Away from Homegrown Tools & Excel / Modernizing Quality Control Through LIMS
- Successful Lab Digitalization by Defining Clear Selection Criteria
- Best-Practice Methodology for LIMS Selection
- Planning a Successful Implementation

Comparison Excel vs LIMS

Feature	Excel	LIMS
Data Entry	Manual, prone to errors	Controlled, validated input fields
Audit Trail	Not available by default	Full audit trail of all changes
Electronic Signatures	Not supported (or very limited)	Built-in, compliant with 21 CFR Part 11, ISO, etc.
Access Control	Basic password protection	Role-based, secure, centralized
Version Control	Manual and error-prone	Automatic, controlled document/version management
Compliance	Difficult to validate, not compliant by default	Designed for regulatory compliance
Integration with Instruments	Manual copy-paste or macros	Direct instrument interfacing and automated data capture
Workflow Enforcement	None	SOP enforcement, step-by-step process control
Data Analysis/Reporting	Manual, static charts	Automated reports, dashboards, real-time analytics
Scalability	Limited (slow with large data sets)	Scales with organization size and complexity
Collaboration	Difficult with multiple users	Multi-user, real-time collaboration
Data Integrity	Easily corrupted or overwritten	Strong controls to ensure data accuracy and reliability
Downtime Risk	High (file corruption, user error)	Low (with proper backups and system design)
Cost	Low initial cost, but high hidden risks	Higher upfront cost, but lower long-term risk/cost

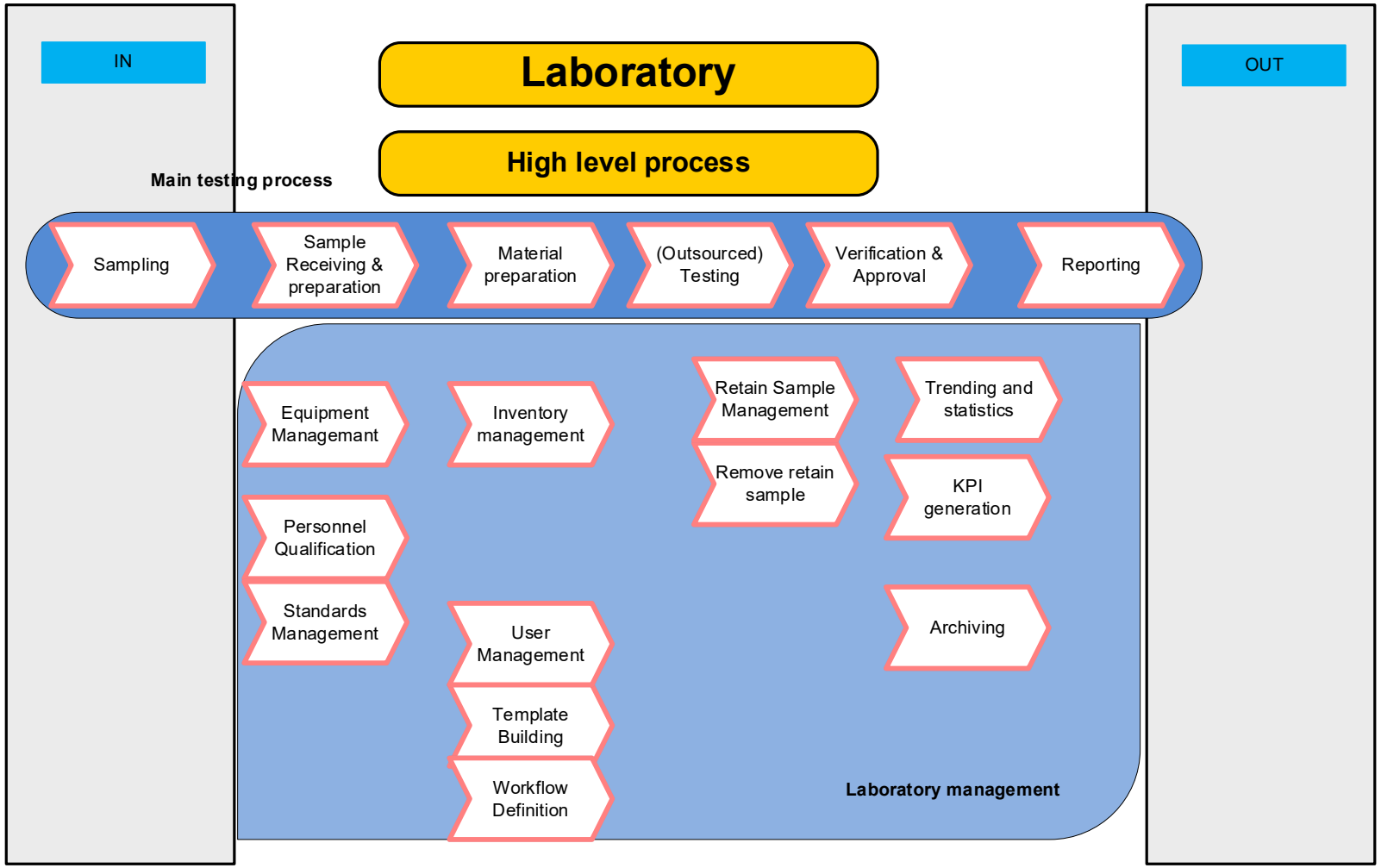
Laboratory Information **management** System

Laboratory is still often a black box for the rest of the organization where only input (money) and output (lead time) is considered.

So, the laboratory must organize its own processes and make them effective and reliable.

LIMS is critical for an effective reliable laboratory

Scope for laboratory – High level



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Must-have vs. nice-to-have features for your operation

- Maybe surprising statements:

> Select on the must haves AND on the ‘important’ nice to haves.
> Select on what you might need the next 5 years.
> You don’t have to implement everything in phase 1.

- What is now a nice to have can be a must have tomorrow!
- Last 5-10 years we did not put “ MoSCoW” in RFI/RFP/RFQ. If it is not important enough to select on, don’t put it in the requirements. We don’t create an implementation URS for the selection.

- And many LIMS solutions have most of the must haves. A mature market.

Types of requirements

Functional

- About processes and activities
- Must haves – nice to haves

Demo scenarios are very important in our selection methodology!!

Non-functional

- Often technical, often from IT, but not only by definition (project management, language, ….)
- Mix of knock-out/clear and fuzzy requirements

Compliance

- Knock-out must haves

Pre-defined functionality list

The pre-defined functionalities are split into the following groups:

- Basic LIMS/ELN functionality;
- Reporting & Printing;
- Compliance;
- Equipment;
- Modules & Specials;
- Configuration;
- Others.

The list is created from many years making and answering URS/RFP documents.

Basic LIMS functionality

- Individual registration (sample, project, test)
- Automated registration (sample, project, test)
- Sample-splitting (subsample generation)
- Scheduling of samples, test and/or projects with flexible frequencies
- Result entry with E-notation
- Input masks
- Mandatory result or information entry
- Approval workflow and authorisation management with users and user groups
- Worklist (dynamic)
- Runs - Series - Templates (Static: e.g. for instrument connections)
- Comment to objects
- SOP linked
- Management by exception workflow
- Grouped samples (projects, studies, jobs, orders, contracts, batches, etc.)
- Result calculations
- Plausibility check for data entry
- Result formatting
- Default results
- Sample turn around time calculation
- Out of spec alarm handling
- Out of trend alarm handling
- Shelf Live - Due time functionality and workflow
- Re-analysis, re-sample and reflex testing
- Cancelling
- Priorities of samples and tests
- Scheduling tests, samples, equipment, technicians with calendar management
- Sensorial examinations

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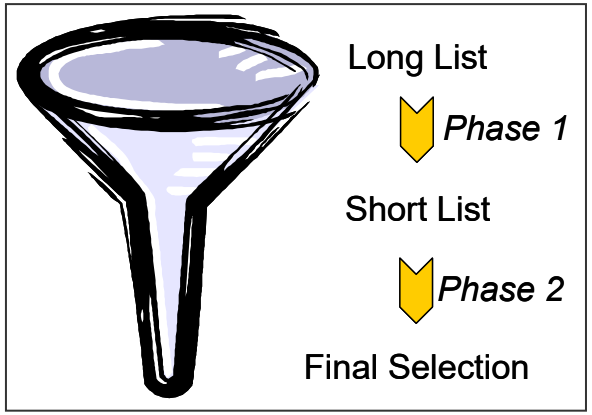
Objectives

- Objectives: acceptance and active participation of all involved
- Convinced of
  - Selection of "sufficiently good" LIMS product
  - Transparency and validity of the selection process itself

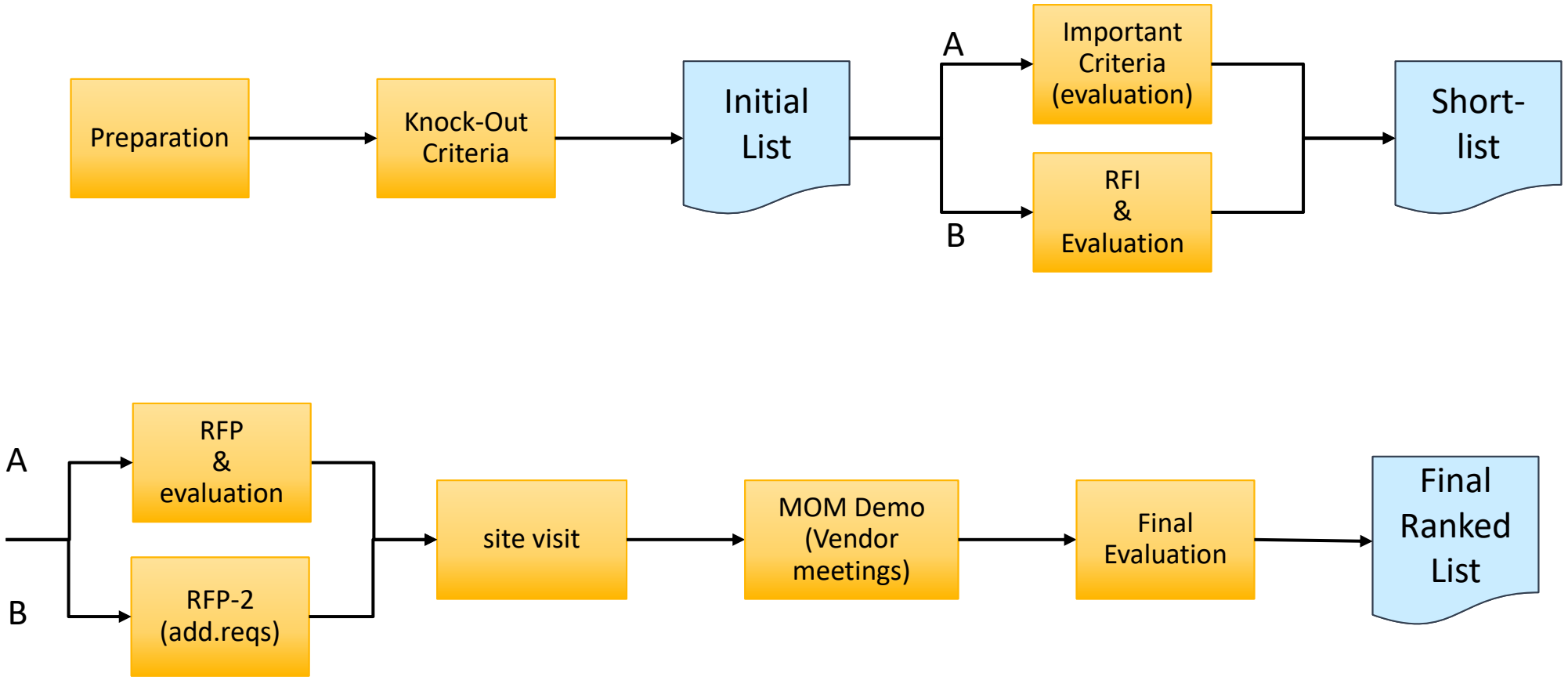
Phases

1. Determine shortlist
2. Find the champion



Overview

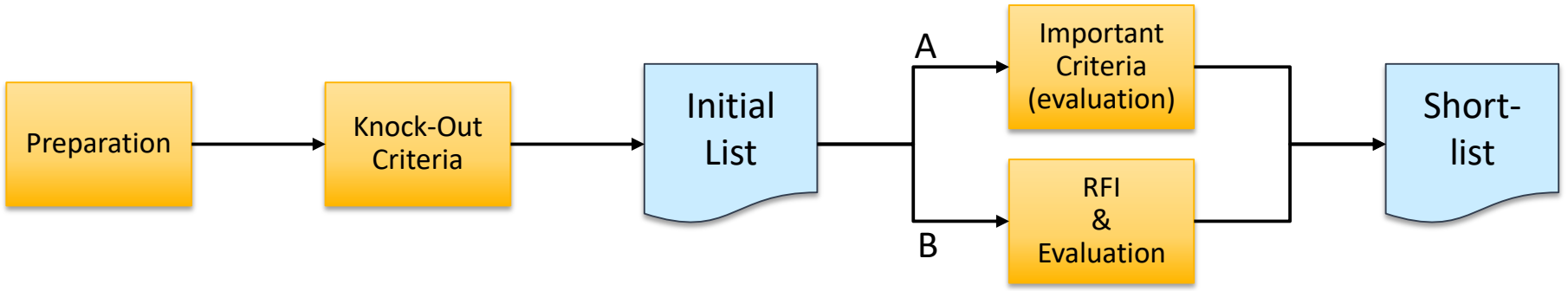
MOM Product Selection: Best Practices



Prerequisites for Selection

- Vision and strategy
- Benefits/business case
  - SMART objectives
- Architecture blueprint
  - To-be business processes
  - Application landscape
  - Technology preferences
- Road map (generic)
- Clear scope and focus
- Known risks

Initial List

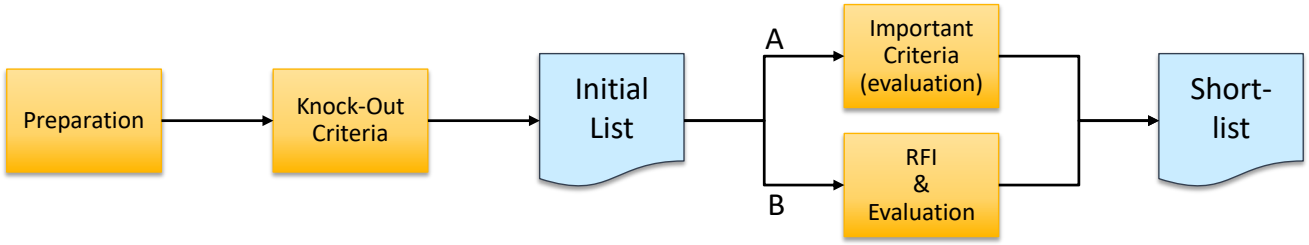


- Initial LIMS vendor lists
  - I start with a list of about 10 to 15 LIMS vendors
  - Sometimes SAP also wants to participate with SAP-QM

Sometimes there is ‘trust’ and companies ask to create a shortlist with 3-5 vendors immediately. These will receive the RFP in the next phase.

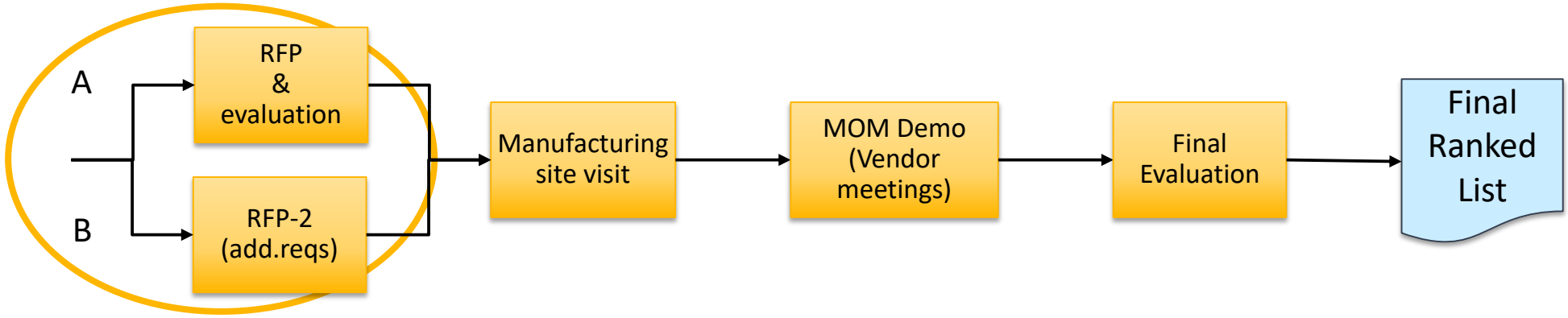
Description

Selection Step 1: Create Short-list



- In the Selection, we distinguish two phases: “Create the short-list” and “Find the Champion”. As mentioned, the preparation leads to determination of the business drivers, expected benefits, scope, future improved ways-of-working and architecture.
- From the results of those preparation steps, knock-out and other important criteria for the LIMS solution can be derived. Today, hundreds of LIMS solutions are available on the market. The knock-out criteria are used to create an initial list, which may comprise up to approx. 10 – 12 LIMS solutions.
- Dependent on the defined other important criteria and the available information about the LIMS solution in the initial list, basically two alternatives exist. (A), it is possible to reduce the number of options to a short-list with approximately two to four, based on the already available information. (B), we need to ask the vendors of the initial list for additional information. That can be done by creating a Requirements Document or Request for Information (RFI) and evaluating the response of the various vendors.
- Typical content of a Requirements Document is:
  - Objectives of the MOM solution implementation,
  - Description of your business processes and the focus (scope) chosen for the project(s),
  - Required functionality (e.g. referring to ISA-95) and non-functional aspects,
  - Interfacing with other systems,
  - List with relevant questions.
- LIMS selections typically follow (B)

Requirements Document



- Requirements document (RFP)
  - Objectives for LIMS implementation
  - Business processes within scope
  - Required functionality
  - Interfaces with other systems
  - Few relevant (open) questions
  - Specific test cases (small), scenarios

How does the vendor commit to your success!

Evaluation Matrix (Example)

Other non-functionals				Product X		Product Y		Product Z	
Nr.	Criteria	Description	Factor	Score	Result	Score	Result	Score	Result
1	Pricing	Total license fees (pilotproject and all roll-outs)	4	4	16	4	16	3	12
2	Pricing	Annual maintenance & support fee	3	3	9	3	9	3	9
3	Pricing	Rate card fees	3	4	12	3	9	4	12
4	Pricing	Other variable costs	2	4	8	4	8	3	6
5	Maintenance & support	Robustness of supplier services & support model	4	4	16	4	16	4	16
6	Maintenance & support	Standard maintenance	3	4	12	4	12	4	12
7	Maintenance & support	Customer support / help-desk	3	3	9	3	9	3	9
8	Maintenance & support	Training	2	3	6	4	8	4	8
		Sub total (absolute)	120	29	88	29	87	28	84
		Sub total (relative)		72,5%	73,3%	72,5%	72,5%	70,0%	70,0%

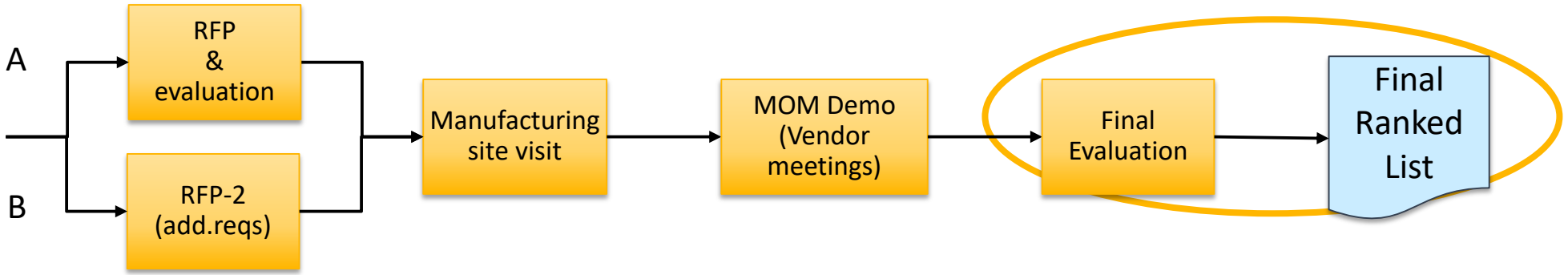
Implementation plan incl. pilot project				Product X		Product Y		Product Z	
Nr.	Criteria	Description	Factor	Score	Result	Score	Result	Score	Result
1	Methodology	Implementation methodology	4	3	12	3	12	3	12
2	Roles	Are roles of the vendor and us clearly described?	3	3	9	2	6	2	6
3	Project plan	Is the implementation/project plan clear (activities, roles, risks, etc.)?	3	4	12	3	9	3	9
4	Integration approach	Approach test interfacing with level 2 and level 4 systems	2	4	8	3	6	4	8
		Sub total (absolute)	60	14	41	11	33	12	35
		Sub total (relative)		70,0%	68,3%	55,0%	55,0%	60,0%	58,3%

Summary			Product X		Product Y		Product Z	
	Section	Contribution (%)	Relative Result	Result	Relative Result	Result	Relative Result	Result
	General aspects	10	71,4%	7,1	69,2%	6,9	68,6%	6,9
	Business objectives	20	76,3%	15,3	69,7%	13,9	70,90%	14,2
	Functional requirements	20	79,5%	15,9	76,3%	15,3	77,5%	15,5
	Technical requirements	15	71,7%	10,8	66,5%	10,0	70,0%	10,5
	Other non-functional aspects	15	73,3%	11,0	72,5%	10,9	70,0%	10,5
	Implementation plan, incl. pilot project	20	68,3%	13,7	55,0%	11,0	58,3%	11,7
	Total	100		**73,7%**		**68,0%**		**69,2%**

Apparent accuracy?

Significant?

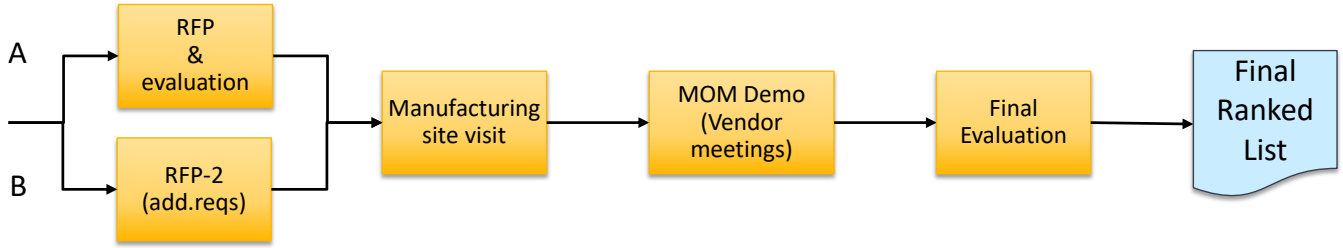
Find the Champion!



- Final choice (ranking)
  - Functional:
    - Does the LIMS product fit to demands?
  - Technical:
    - Sufficiently reliable
    - Fit to your company's strategy and policies
  - Financial
  - Cultural
  - Are you convinced you will be successful together?

Short Description

Selection Step 2: Find the Champion



- After the acceptance of the short-list, again the same two alternatives. If the short-list is created without communication with the vendors (A), they need to be informed through the Requirements Document. Typically, at least two topics are added in comparison to the RFI: explicit scenarios to be demonstrated at the meeting with vendors and a clear budget indication. The scenarios represent certain parts of the quality operations, which are decisive for the ultimate success. Otherwise (B), we need to share requirements including the two afore mentioned topics with the short-listed vendors.
- The vendors are invited to visit the site, to get a better understanding of the objectives, the processes in scope, etc. During the vendor meetings, the scenarios are demonstrated and all question from both the manufacturer and the vendors are answered to create mutual understanding.
- The final evaluation will result in a list in which the solutions are ranked on added value, which is the difference between expected benefits and the total cost of ownership for a number of years (not just the initial investment).

Five Most Made Mistakes

1. Too much or too little in the "Request for" documents.
2. Not getting enough organizational participation.
3. Buying a “product” instead of a “solution”.
4. Not buying on Total Cost of Ownership (TCO).
5. Forgetting about the future.

The Takeaway: Process is Key

A solid vendor selection process is as key
to your Digital Transformation efforts
as any other strategic decision or activity.

Source: LNS Research

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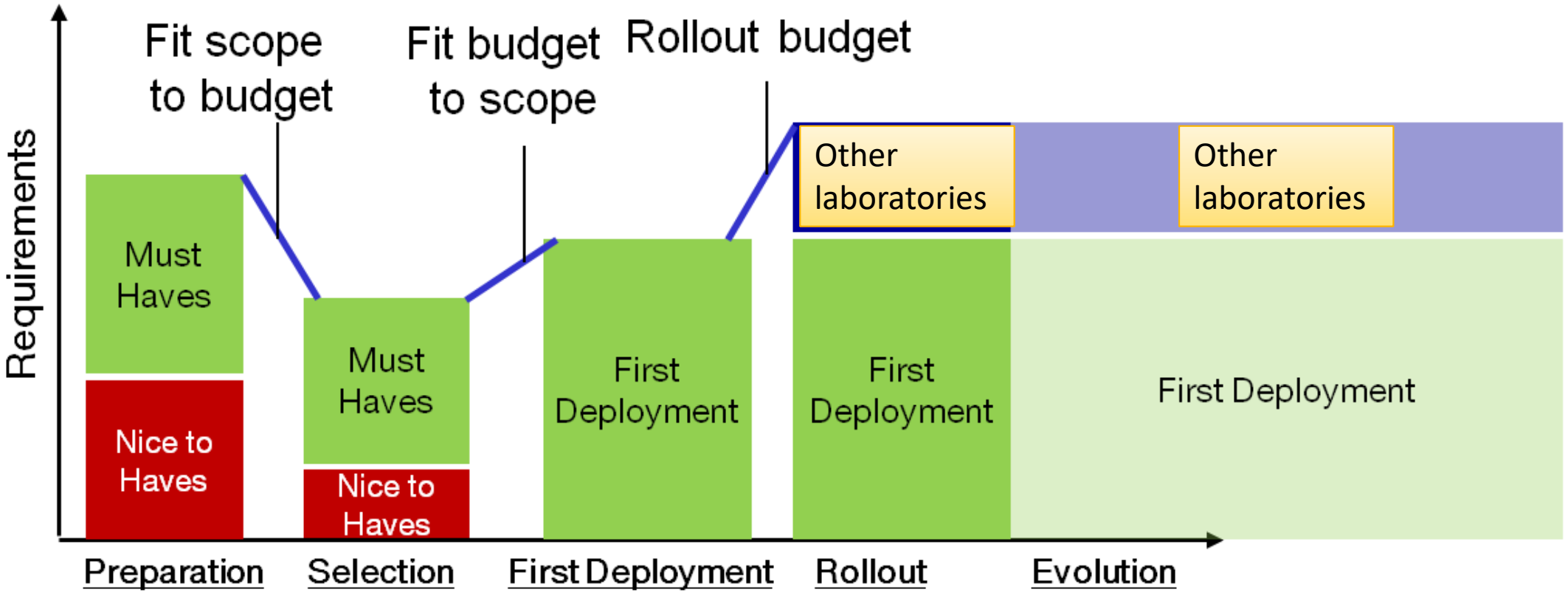
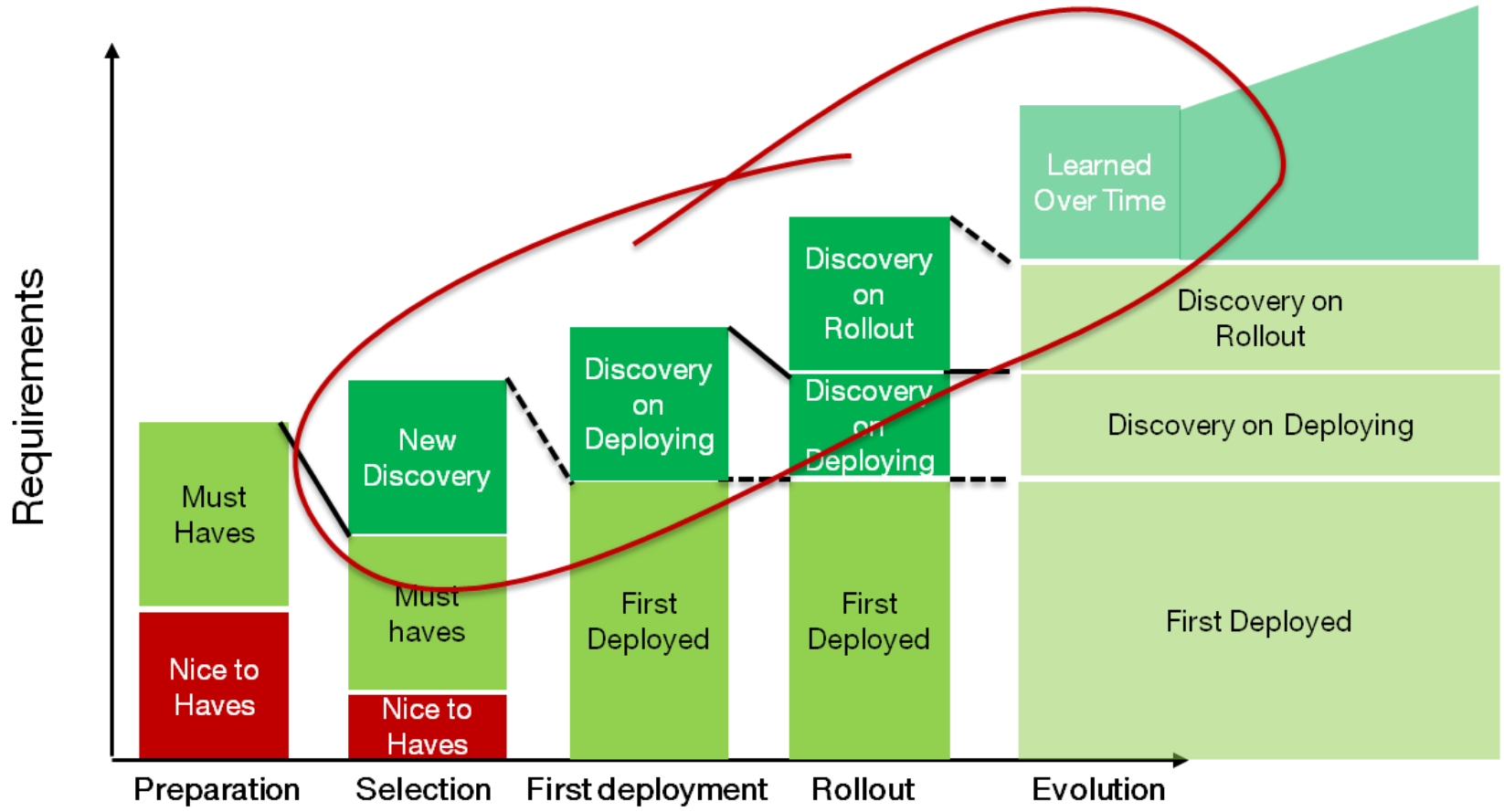
The Illusion

"When we finish the project, we're done"

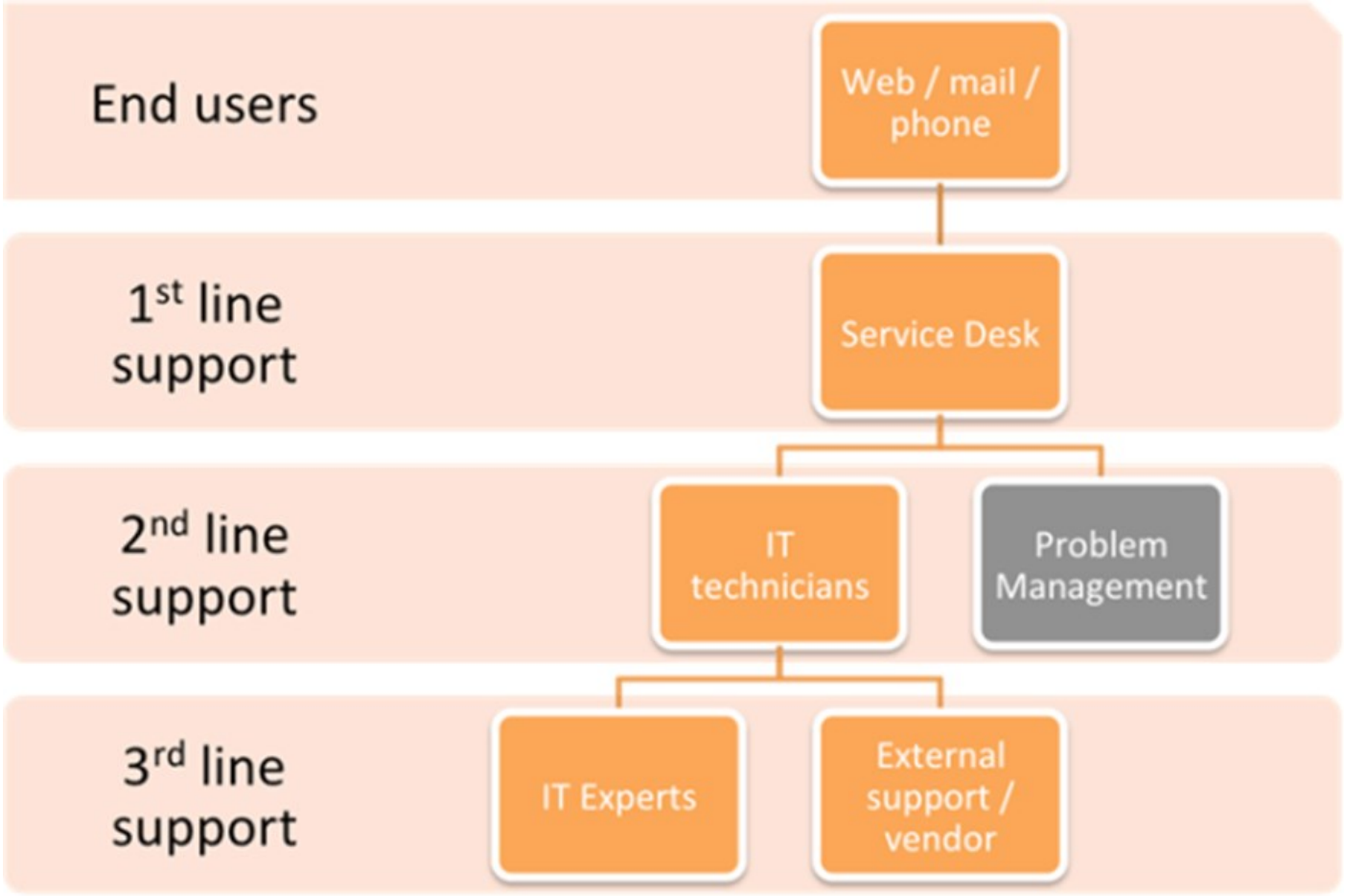


The reality

”Progressive Insight” drives needed scope changes



Incident management (ITIL)



Want to Know More?

Ask Now or Later …

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