

Process Review - Exploring the potential of PAT for pharmaceutical manufacturing

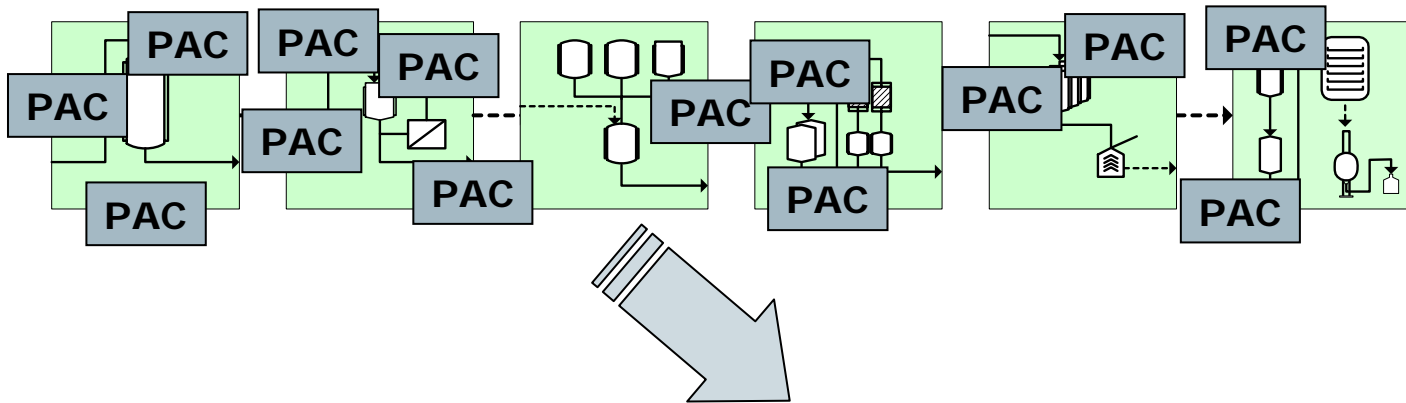
NNE A/S, Process Consulting

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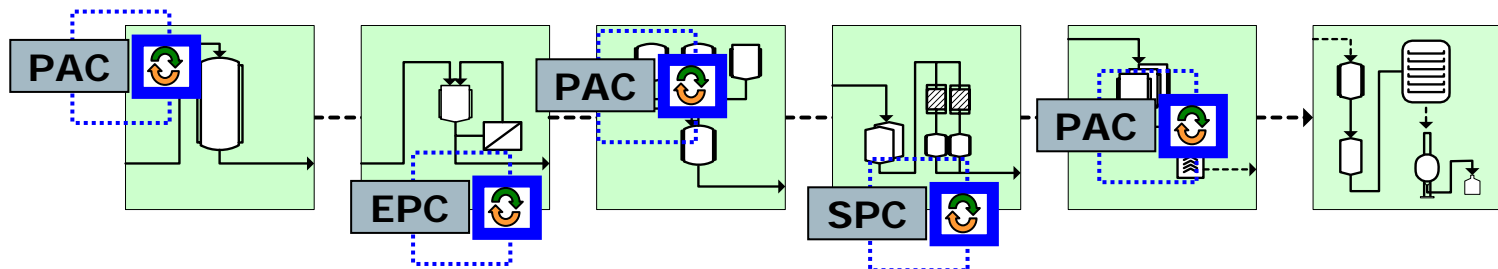
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Manufacturing with PAT

Instrumentation focussed, process analyser solution,
measurements used for monitoring not controlling



Risk based, Lean, Smart PAT solution



- PAC** Process Analytical Chemistry (Process Analyser)
- EPC** Engineering Process Control (simple measurement)
- SPC** Statistical Process Control

Process Review - Objective

- Identify possible causes for undesirable variation
- Identify opportunities for improvement
 - Efficiency / equipment utilization / downtime
 - Scrap / rejects / non-conformances / Out Of Specifications
 - Not capable processes
- Identify CQA and CPP
- Select the most cost efficient optimization projects

Process review - methodology

1. Process overview

- Define the process
- Impressions – problems and issues (upstream)
- Focus on criticality –product to process criticalities

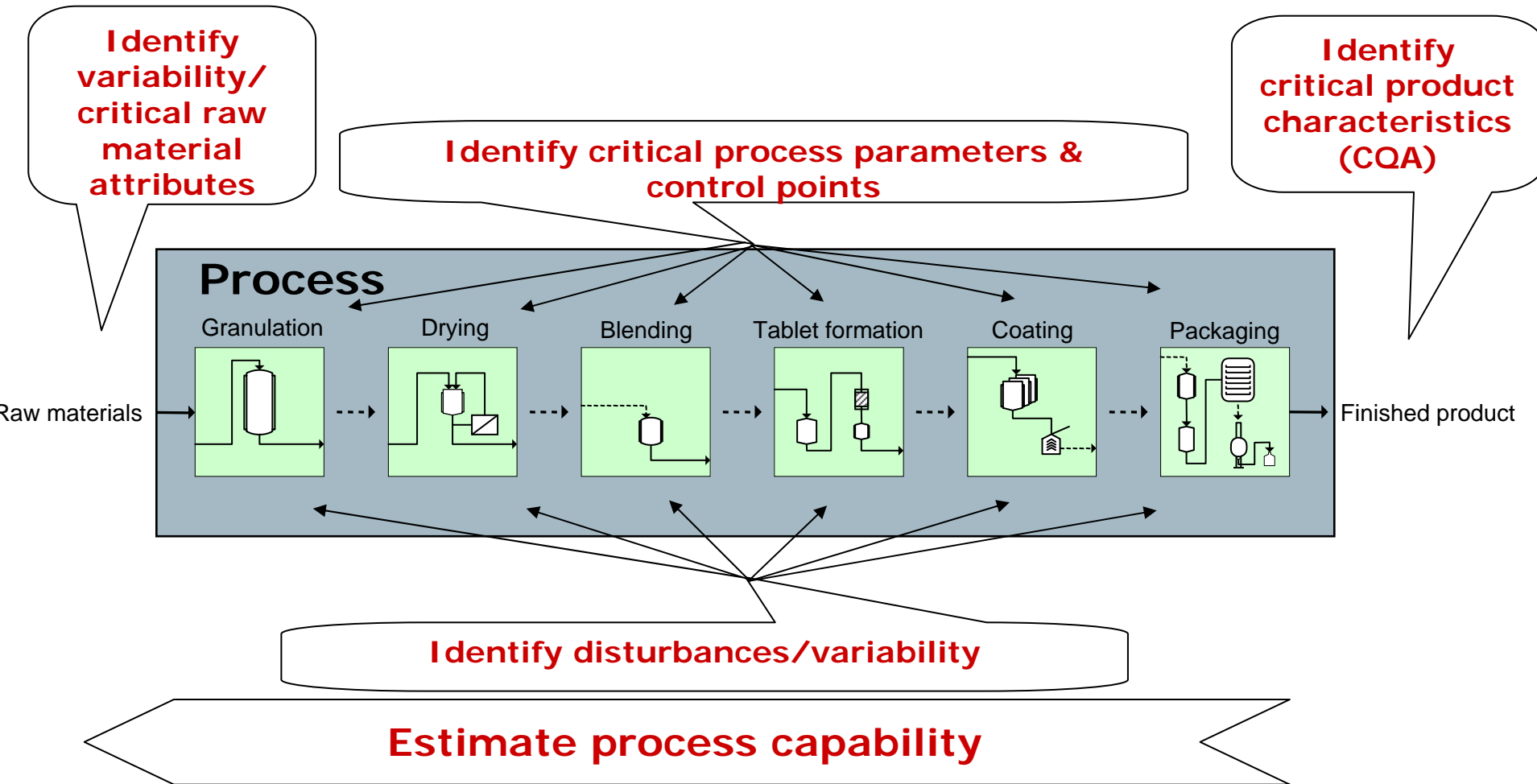
2. Collection and evaluation of data

- Collecting, formatting and analyzing all data (process, lab, batch etc.)
- Evaluate deviations and scrap for possible causes
- Process variability & capability analysis

3. Define improvement projects

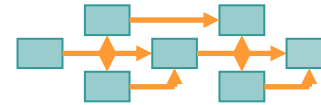
- Based on the data evaluation
- Raw & in-process Materials - id CQA & CPP
- Opportunities for on-line monitoring and control
- SOP's – quantity and quality

Process Review - Risk based approach

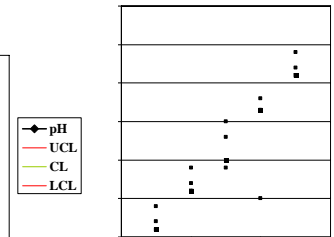
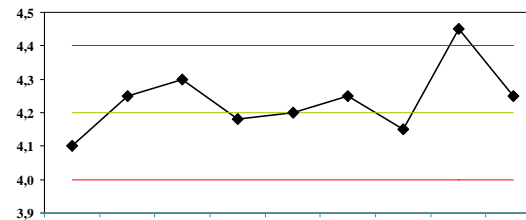
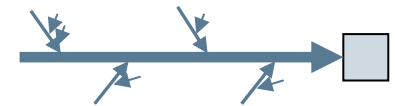
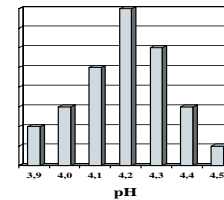
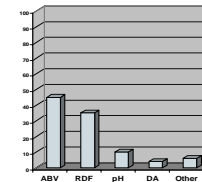


Process Review Tools

- Process Flow Diagram
- Value stream mapping (LEAN technique)
- Risk Assessment
- Statistical Process Control
- Basic statistics
- The Seven Tools (Ishikawa 1985)
 - Pareto Analysis
 - Cause and Effect Diagram
 - Stratification
 - Check sheet
 - Histogram
 - Scatter Plot
 - Graphs and Shewhart Control Charts
- Multivariate data analysis



A					
B					
C					
D					
E					
F					

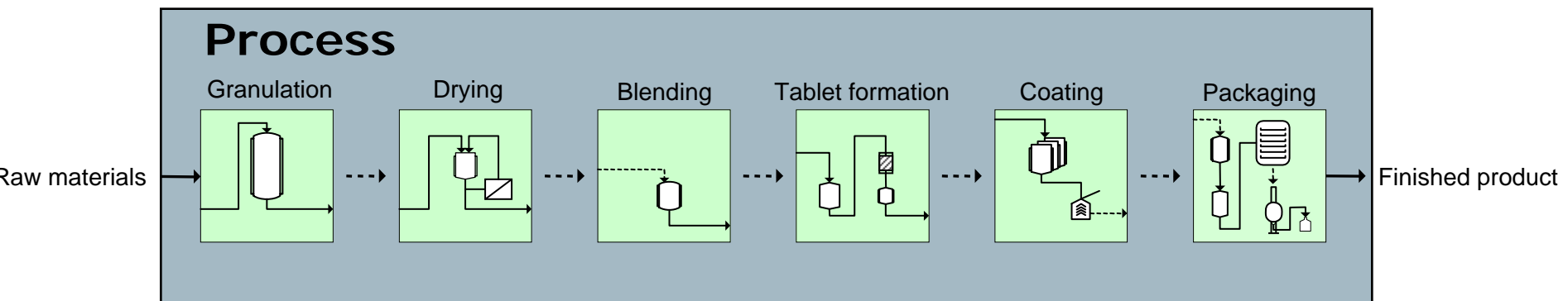


Case Study: Secondary Manufacturing Process Review

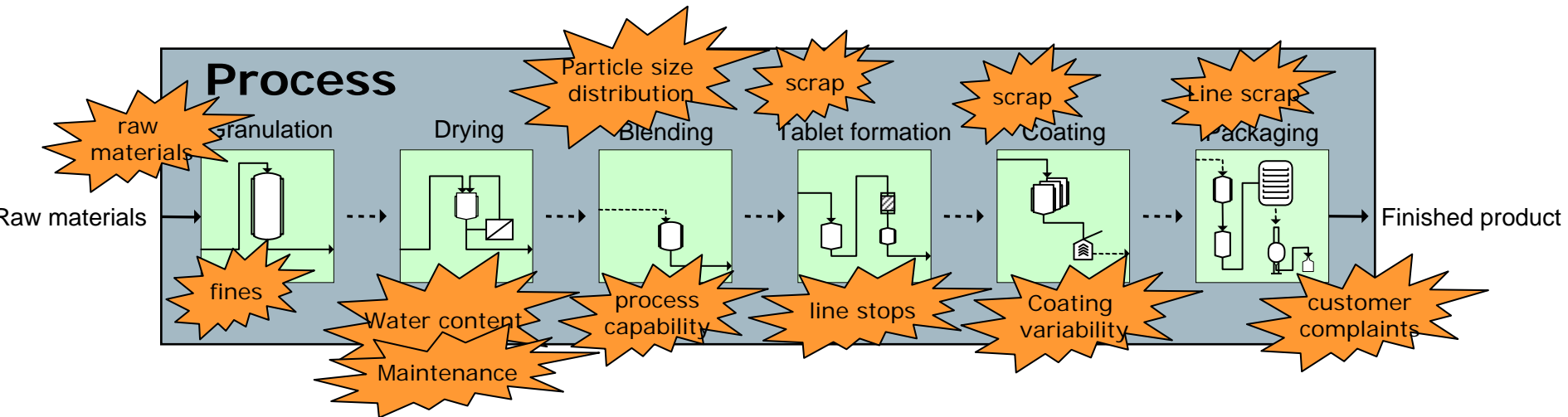
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The Secondary Manufacturing Process



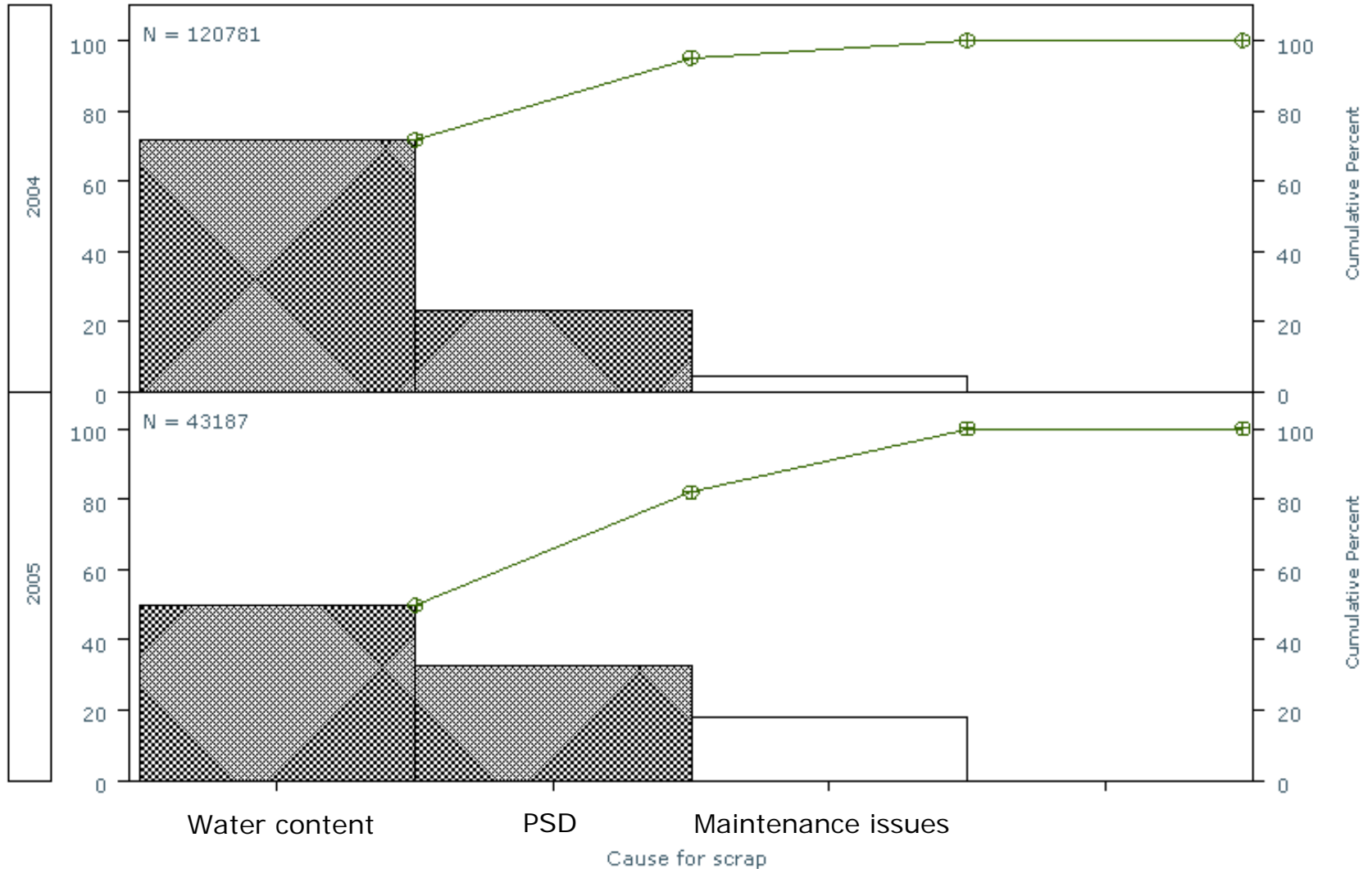
Process Performance - Impressions



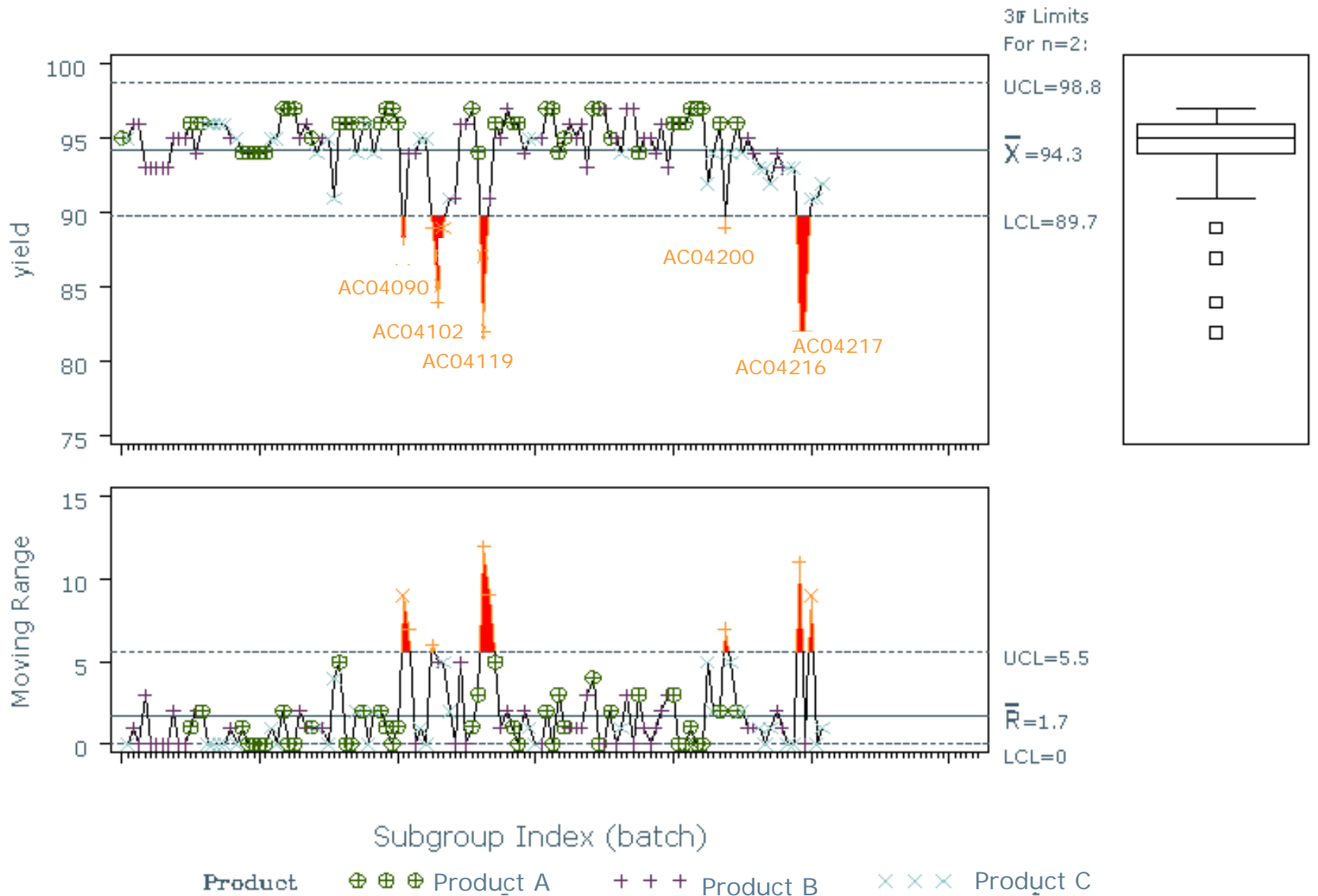
Vital to link experienced process experts to result of data analysis

Product A, Process step B

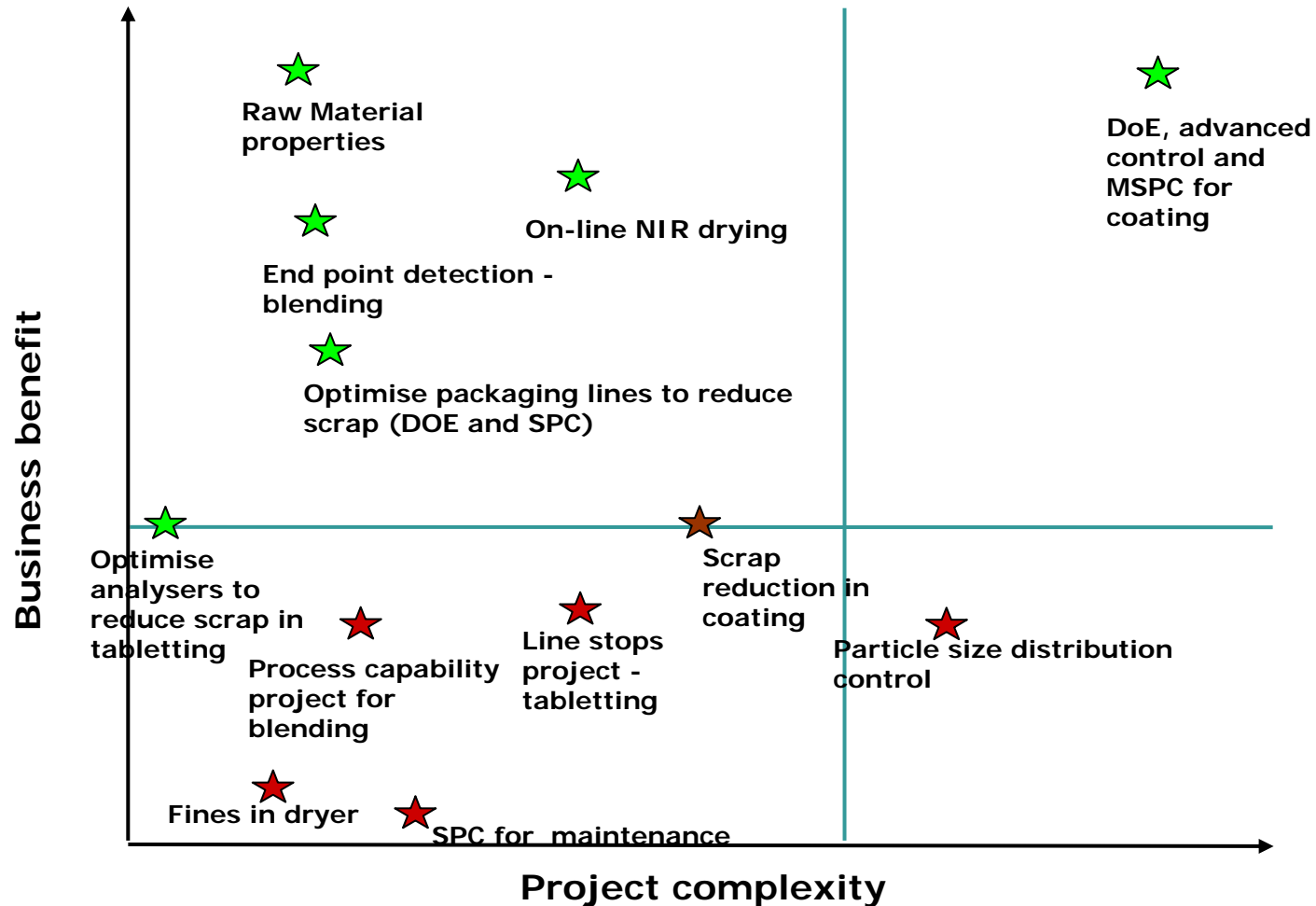
Pareto Charts - Causes for scrap Jan 2005 -Jan 2006



Yields 01jan04-31dec04 Process step SH

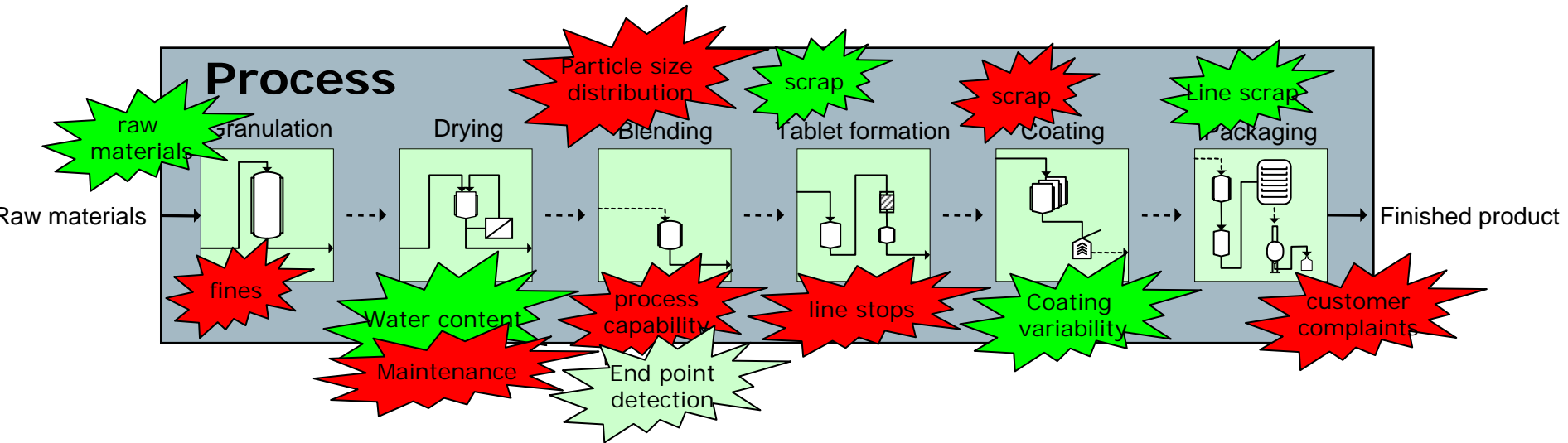
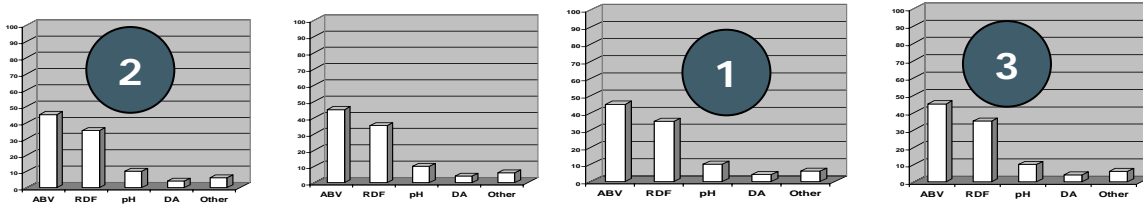


Project Prioritisation – Business benefit and project complexity



Process Performance - Impressions

Prioritised opportunities for improvement



Process Review - Benefits

- Using process expertise to provide potential projects followed by data analysis is both quick and realistic
- Highlight problem areas and opportunities for improvement
 - *Assumed issues are not always confirmed*
 - *Unknown opportunities for improvement identified*
- Prioritised list of improvement projects
 - *Business cases for PAT projects*
 - *Return on Investment figures to get management approval and funds*
- Improved process understanding - Opportunity to 'talk' about the process

Summary – Process Review

- All about money!
- Find the best optimization or improvement projects for the funds available
- Control and adjust the process rather than monitor it
- Minimum of investment in resources,
- Use knowledge and simple tools
- Use current data, knowledge and process experts
- Invest in data analysis capabilities

