Do we need a PAT-IT system infrastructure?

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Introduction

- Forum on PAT, “salesmans” talk about an IT-project?
- Technical Project Lead
  - PAT group, QC labs, Novozymes since 2010
  - Working with PAT, and PAT IT infrastructure since 1998
  - M.Sc. Physics, University of Aarhus, 1995
- Novozymes, world leader in industrial enzymes – but also a long time user of PAT (>20yrs work, and since 2005 PAT has been used routinely for batch release).
Novozymes in brief

- World leader in Industrial Enzymes & Microorganisms
- Enzymes account for > 90% of turnover
- Market leader in all main industries
- More than 700 products used in 130 countries in > 30 different industries
- More than 6,500 granted patents and pending patent applications
- Main production in USA, China and Denmark
- Sales DKK 9.72B (FY2010)
- Strong profitability (21.8% in operating profit margin FY 2010)
- More than 5,400 employees

Enzymes for industrial use - market size approx.* ~DKK 19 billion

DSM 6%
Danisco 21%
Novozymes 47%
Others 26%

Source: Novozymes 2010 estimates
PAT in Novozymes in a historic perspective

...in short, >20yrs of PAT
currently >70 active calibrations
8 FT-IR at-line, 1 FT-NIR on-line spectrometers
PAT group anchored in QES, 4,5 FTE (until yesterday!)
Setting the scene

- PAT is essentially about avoiding time-criticality

*hurtigmetoder*
The ‘fast’ loop: AT-line

FT-IR instrument in production
Bring sample to instrument
Measure
Result OK’s production lot

EASY – only a few details

Identify sample, determine instrument settings for this product,
setup instrument (take background), use correct prediction model,
test goodness of result (leverage, residual, valid (working) range of model)
Do it once more – we require duplicate determinations
Transfer result to the MES (in our case SAP)
Check if this sample needs to be sent to lab. (bad determination, or every 5th)

Done by process-operator (24/7)
The ‘fast’ loop: ON-line

Tightly integrated with the PCS system – controls start/stop, background results of predictions, and goodness of predictions written to PCS and to datahistorian

FT-NIR instrument in granulation
Start instrument
Measure

EASY – only a few details

Need to extract samples for “off-line” analysis
As close to sampling point as possible, and need to know the EXACT sampling time, and the Physical Sample Number (LIMS no.) assigned
Registering should be automatic – and NOT rely on sheets
Interfaces

AT-line:
- Physical sample id. (barcode)
- MES (SAP)

ON-line:
- PCS
- Data-historian
- MES/LIMS (SAP)
The ‘slow’ loop
The ‘slow’ loop cont’d

Recalibration
1. Find all recent laboratory determinations
2. Find associated spectra (USB stick?)
3. Build spreadsheet
4. Use chemometric s/w to build and validate new model
5. Put new model into operation (USB stick?)

Item 4 is the fun part, but the other items take
The majority of your time 😞
Interfaces

AT-line:
- Physical sample id. (barcode)
- MES (SAP)

ON-line:
- PCS
- Data-historian
- MES/LIMS (SAP)

Calibration analysis (model monitoring):
- Reporting

Recalibration:
- Chemometrics software

Atypical IT system, sitting between LIMS, manufacturing IT, and Office IT. Complex, many stakeholders, hence NZ has chosen to man their new PAT IT project with PL + tPL.
Do you need a PAT IT infrastructure?

- If you only have a few (stable) calibrations MAYBE NOT
- Having >70 calibration models DEFINITELY

2003: Novozymes 1st generation PAT IT infrastructure
   DIMMS

2009: ZyPAT project
2011: ZyPAT II project
ZyPAT I

Motivation:
- PAT identified as a strategic initiative in the corporate strategy
- Teknologisk Institut shutdown the DIMMS group – no support
- New applications in the pipeline (successes create demand)
- Ensure global alignment (best practices / governance)

Goal:
- Prepare a **User Requirement Specification (URS)**
- Identify possible vendors
- Ask selected vendor(s) to prepare a Functional Specification (FS)
- Select final vendor
ZyPAT I project

- URS completed June 2010 (1yr)
- No vendor provides at-line OOTB
- OPC ADI and OPC ADIc
- FS prepared for:
  - SIEMENS SIPAT
  - ABB xPAT
- ABB chosen early 2011
ZyPAT II

- Project deliverables
  - PAT governance set-up defined including
    - Roles, responsibilities and processes defined for development and maintenance
    - Support agreement
    - PAT standard
    - Fall back procedure
    - PAT IT organization
  - Appointed and trained users
  - Approved and documented PAT system (as defined in specification)
    - PAT system is approved for global product release
    - PAT data are accessible in DCS systems (Procos, SATTLINE)
    - PAT system is robust, flexible and user friendly
  - Proposal for wave II
Network

- Proposal for a global ZyPAT network architecture
- Tying together different so far unconnected networks
- Different regimes, with vastly different SLA
PAT governance during project phase - from idea to go-live
PAT governance during operation

- Operation
  - Calibration
  - PAT data use/data-mining
  - Model surveillance PAT vs LAB
  - Use of PAT results
  - Software error / maintenance
  - Hardware error / maintenance

AS IS
- PATgrp
- PATgrp
- PATgrp
- LoB
- PATgrp
- PATgrp
- LoB

TO BE FG
- Support set-up TBD

TO BE FG
- MPP
- LoB
- LoB
- LoB

Support set-up TBD
ZyPAT II

Status 31st May 2011:
- Contract signed with ABB mid May
- Project group has started working
Latest news: The top bosses are convinced PAT is the future!!

where MPP is present to integrate the touch the world into daily life and concrete behaviors. During the MPP-Man discussion of the values, Connect to create and Unlock Passion were identified as the values where MPPMan saw the biggest gaps compared to where we are today.

For now MPPMAN has initiated activities concerning how to define Connect to Create in MPP and how to work with Unlock Passion. If you follow the intranet news you will soon find a more detailed article about the coming value workshops.
The PAT group = the fighters 😊 what do we do?

- Feasibility studies – lab/data analysis
- Data collection (SAP)
- Model surveillance - calibrations
- Develop IT system
- On-line implementations

- Lobby!
- Communicate
- Challenge lab...
QUESTIONS?

Practical detail - only attending morning session
Thank you!