

Quality Control & Quality Assurance

Our goals were to reduce lead-time, keep our delivery liability, secure high quality products and meet our regulatory demands. We needed to be in control of the quality process and meet the target to get it "Right first time".

Automation improved the level of documentation, it reduces the number of human errors; provided us the ability to recognize errors and make immediate corrections. We also saw improvement in overall job satisfaction. Automation reduced the amount of unilateral repetitive work; reduced exposure to solvents used; with less over-time and stress.

Summary

Evaluation of the total analytical process for your products is critical. You should determine the optimal number of samples in order to eliminate bottlenecks. The robot is an extra resource and coupled with automation for complicated sample preparation such as multiple dilutions. Try not to fill up the automation solution with samples; this will create bottlenecks.

References

Ulrik Tolderlund, Analytical Chemist (Multidose), ulto@lundbeck.com
Mikael Rasmussen, Analytical Chemist (TPW), mir@lundbeck.com
"The Goal", by Eliyahu M. Goldratt
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Application Note

Automation of Pharmaceutical Bulk Analysis to improve Lead-time, Delivery Liability, Quality and Working Environment

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Introduction

As a major pharmaceutical company focused on specific goals to improve quantities of Bulk chemicals kept in stock, we looked to automation to help achieve our goals over a 3-year period. Our objectives were to: improve lead time from an average of 60 days to 3 days, secondly to improve Delivery liability where 95% of batches could be finished within 7 days; continuing to Improve Quality by getting it right the first time and to enhance our work environment by reducing repetitive work in a safe environment. Our directive was to do this with no new resources while creating long-term flexible solutions.



Production Assessment

We determined that we had 4 High Volume Products and 12 Low Volume with the following attributes:

4 High Volume Products

- ❖ Predictable number of batches
- ❖ Continual runs
- ❖ Dedicated equipment
- ❖ Bottlenecks easily detected and eliminated
- ❖ Low level planning

12 Low Volume Products

- ❖ Variable number of batches
- ❖ Variable runs
- ❖ Changing Instruments
- ❖ Bottlenecks vary
- ❖ High level planning

Lead-time Reduction

Automation solutions raise several questions. Can Automation help? Is it only possible to benefit from automation if you have many batches? Here is what we found relative to our bulk product mix:

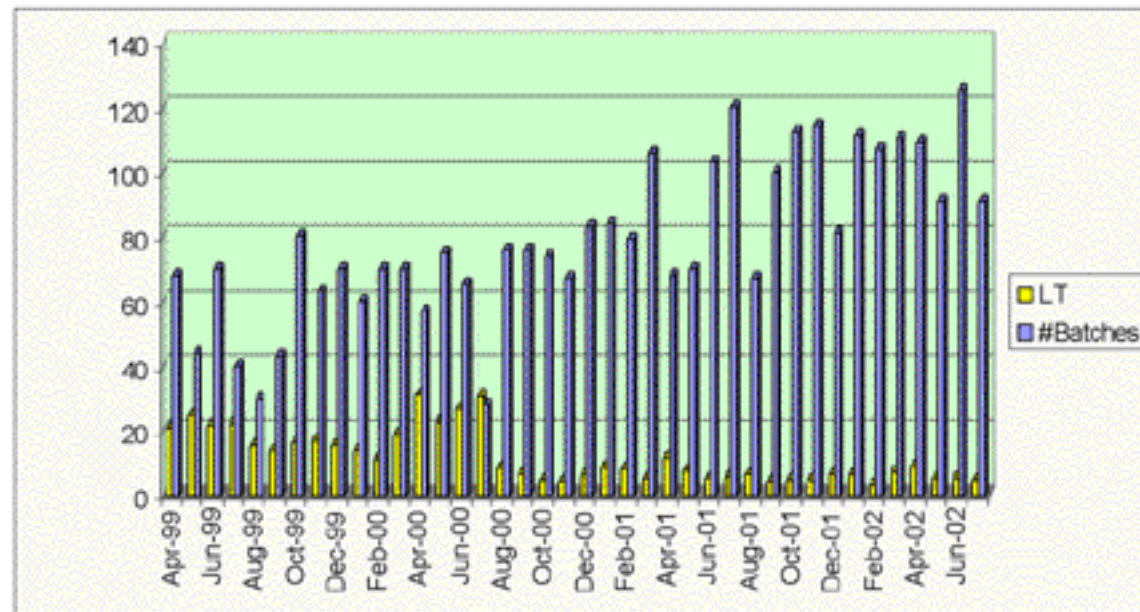
High Volume Products

- ❖ Expand the number of working hours without using shifts
 - Robots can handle samples 24 hours
- ❖ Keep operational costs low
 - Human resources
- ❖ Facilitates planning as time of analysis is constant

Low Volume Products

- ❖ Analysis can be performed at the right time any time during the 24 hours
- ❖ Eases the flow of samples through the laboratory
- ❖ Human errors were almost eliminated resulting in no loss of time

The following chart illustrates the lead time efficiency realized on a Strategic Product:

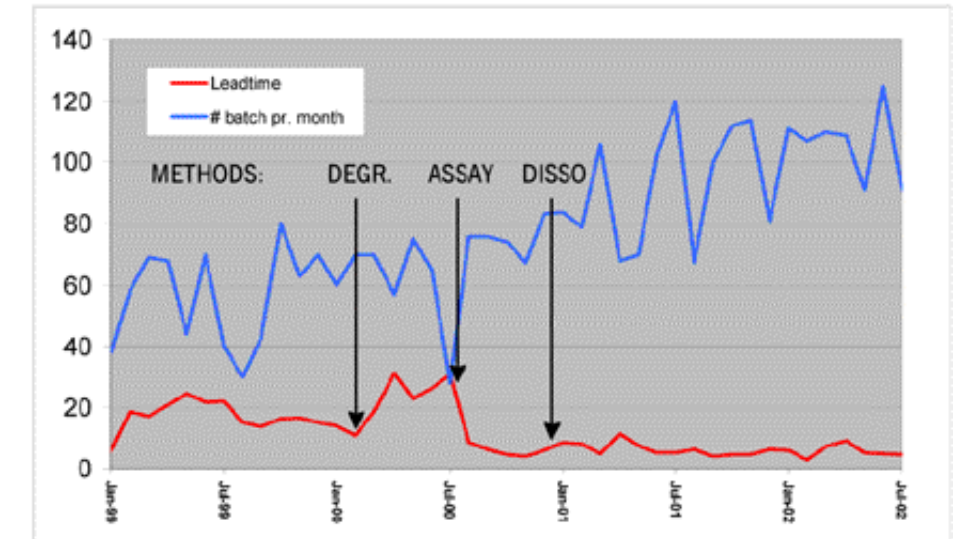


Our automation history to accomplish this:

AUTOMATION HISTORY

- 1997 purchase of "Zymate", customized solution for dissolution testing (†)
- 1998 (Dec.) purchase of TPW no 1 (†)
- 1999 purchase of Multidose no 1 and TPW no 2
- 2000 purchase of TPW no 3 and Prelude
- 2001 purchase of Multidose plus , TPW no 4 and Multidose no 3
- was this as easy as It looks....??

This slide summarizes the time interval when automation was introduced with the number of batches increasing and the lead-time improvement realized.



Delivery Liability

Automation Benefits

Both High Volume and Low Volume Products

- ❖ Analysis can be performed at the right time any time during 24 hours
- ❖ Automation makes it possible to predict exactly when the analyses is completed
- ❖ It eases the flow of samples through the laboratory
- ❖ Provides extra capacity when needed