

International Symposium on
Continuous Manufacturing of Pharmaceuticals
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White Paper # 5

Equipment and analytical companies meeting continuous challenges

Craig Johnston (CMAC)

Session #5 structure

Panelists: Roland Guidat (Corning) Trevor Page (GEA)
Des O'Grady (Mettler Toledo) Saroj Patnaik (Emerson)
Marty Guinn (Pfizer) Craig Johnston (CMAC)

Agenda:

- Introduction: C Johnston 20 min (8:45-9:05am)
- Panel Q+A : All 45 min (9:05-9:50am)
- Closing remarks: C. Johnston 10 min (9:50-10:00am)

White Paper #5: Equipment and analytical companies meeting continuous challenges

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Phil Shering, Martin Guinn, Peter McDonnell

Interviews with Small Medium Enterprises (SMEs) in API space:
AWL, Asynt, CRD, Syrris, Scimed, Semba Bioscience, Fullbrook Systems, Zeton, AMtech

Discussions with wide range of technology companies

White Paper #5: Contents

Abstract

Introduction

Predictions for Take up of Continuous Equipment in Pharma Across Supply Chain

Overview

Cost

Impact of Personalized medicines

Technical challenges for processing equipment and analytical development

Particles

Scalability

Fouling / Cleaning

Derisking

Analytical Challenges

Technical training

Technology companies role in helping accelerating introduction of continuous technologies

Typical Company Business Models

Outsourced Pharma Development Partner

SMEs and Academic Groups Roles in Developing New Cost Effective Technologies for CM

Skills

Partnerships

Problem Statements

Consensus around a dominant design for continuous processes

Common Process Design

Hardware and Software

Business Dynamics

Conclusions and Recommendations

References

A Small Medium Enterprise (SME) Perspective

Predictions for Take up of Continuous Equipment in Pharma Across Supply Chain

Continuous is 5% of business will rise to 30%, 100% part of turnover

Many new companies established - many are small. 10 is the norm - bandwidth

Human factors rather than technical factors are main barrier

Technical challenges

Early adopters try to mimic the batch process (validation) work up more obvious in batch

Physical size of products / process, mechanical strength of components

Multi phase systems

Technology companies role in helping accelerating introduction

Help get lab equipment into engineers hand

Generate case studies and data for business case

SMEs / Academic Groups Roles in Developing New Cost Effective Technologies

Collaborative project and stimulating public funding, ride wave of larger activities

Customer demand dictates time to develop, alliances

Driven by technology and innovations rate than shareholder rewards by providing tools

Literature papers growing. Academics not teaching continuous yet

Consensus around a dominant design for continuous processes

Normal bias towards own technology, sell its own product, some vendors dominant position

Standard fitting, output 4-20mA, Modbus, OPC

Mobile phone chargers not standard cf niche market

Key messages and recommendations

- Early adopters advocacy through case study sharing of business case
- Quantitative study with key industry players
- Co-ordinated collaborative activities
 - Sharing problem statements, validated models, glossary
- Offer integrated solutions
- Shared understanding of the key application development and transfer
- Development of scientific papers, whitepapers and educational/ training
- Stimulate government, industry funding and in kind support from vendors.
- Develop concept of standard process design methodology
- Agreed cleaning and cleaning validation strategies

Long Term Vision

- Decentralized on-time-on-demand production of pharmaceuticals by efficient fully continuous processes (API and secondary manufacturing) operated in well-understood modular equipment.
- No difference between batch & continuous equipment concerning functional qualification
- Portfolio of incremental and disruptive approaches across analytical, control and specific technical challenges
- Cleaning protocols routine
- Deliver modular, dedicated high quality production units, based on the recipe of a required pharmaceutical, on short notice.
- Global Skills agenda
- Truly Open innovation
- Open source software and developed platforms

Learning from other industries



FOOD PROCESSING TECHNOLOGY

Principles and Practice

Second Edition

P. Fellows

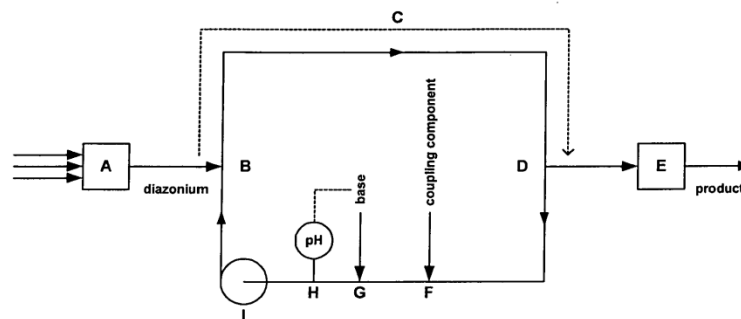
Director, Midway Technology and
Visiting Fellow in Food Technology at Oxford Brookes University

EP1773946 A1

Jul 18, 2005

David Martin Payne,
Douglas John Edwin Spencer,
John Heathcote Atherton,
Zachary Richard Meadows

FUJIFILM Imaging Colorants Limited



Chemtec

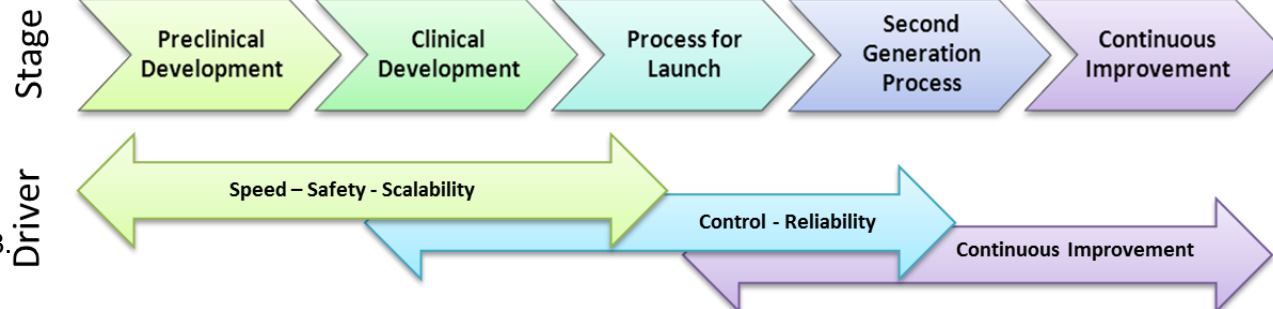
17 case studies

4 most frequent drivers

- safe handling of unstable materials
- speed of implementation
- “right the first time” performance.
- savings in investment

Poehlauer (DSM) et al
Org. Proc.Res.Dev. 2013, 17 (12), pp 1472–1478.

Innov. Pharm. Tech. 2013, 46, pp 52-55.



Key questions and discussion:

An equipment and analytical companies perspective

Predictions for Take up of Continuous Equipment in Pharma

- *How significant is impact of personalized medicines. Science & technology gaps?*

Technical challenges

- *What actually are the most significant challenges?*
 - *Particles, Scalability , Fouling / Cleaning, Derisking, Analytical Challenges*
- *Any key technical challenges missing?*

Technology companies role in helping accelerating introduction

- *How to help best to get lab equipment into engineers hand*
- *How best to work with large Pharma*
- *Thoughts on CMO / CRO role*

SMEs / Academic Groups Roles in Developing New Technologies

- *What is best way to stimulate and accelerate small companies innovation*
- *What is academic training role re equipment and CM*
- *Industry problem statements: Relevance and availability*

Consensus around a dominant design for continuous processes

- *Is it required? Short vs long term vision*
- *Learning from elsewhere*