

International Symposium on  
Continuous Manufacturing of Pharmaceuticals  
MIT May 20-21, 2014

White Paper # 5

## Equipment and analytical companies meeting continuous challenges

Craig Johnston (CMAC)

# Session #5 structure

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**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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## ***Authors :***

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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

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- 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

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- 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

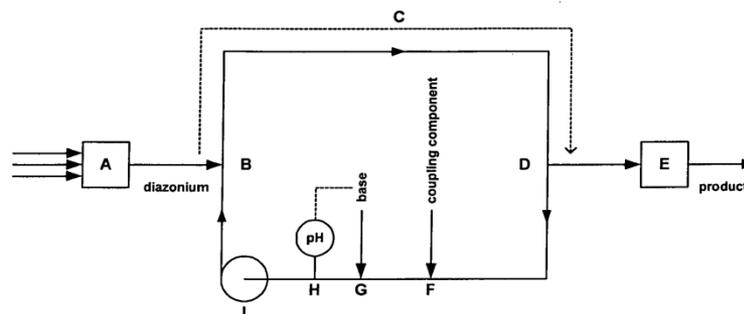
Director, Midway Technology and  
Visiting Fellow in Food Technology at Oxford Brookes University

EP1773946 A1

Jul 18, 2005

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

FUJIFILM Imaging Colorants Limited



Chemtec



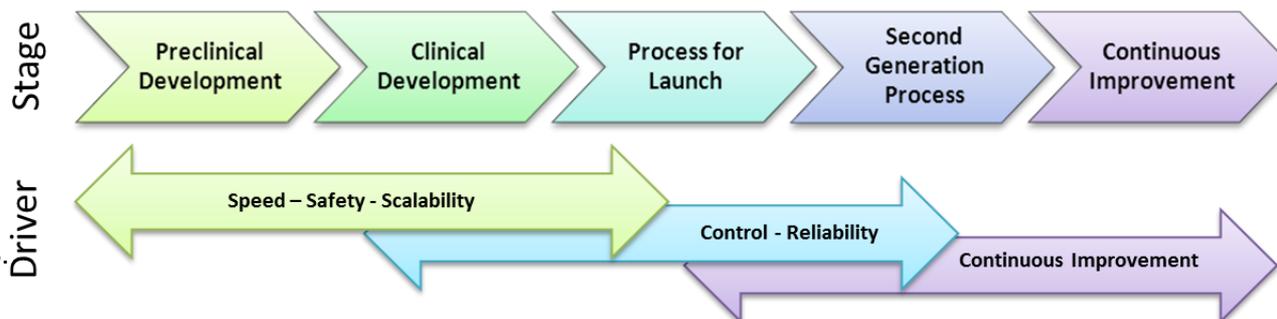
17 case studies

### 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*