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ADDoPT PMC

March 6<sup>th</sup> 2017



#### **Collaboration Makes Sense...**

Being in a band is always a compromise. Provided that the balance is good, what you lose in compromise, you gain by collaboration. *Mike Rutherford* 

Good design begins with honesty, asks tough questions, comes from collaboration and from trusting your intuition. *Freeman Thomas* 

It is the long history of humankind (and animal kind, too) those who learned to collaborate and improvise most effectively have prevailed. *Charles Darwin* 

Alone we can do so little; together we can do so much. Helen Keller

If everyone is moving forward together, then success takes care of itself. Henry Ford

Many ideas grow better when transplanted into another mind than the one where they sprang up. *Oliver Wendell Holmes* 

Politeness is the poison of collaboration. *Edwin Land* 

The secret is to gang up on the problem, rather than each other. Thomas Stallkamp



### **A Brief History**

- Established 2011, Industry demand led
- Portfolio of Funded Programmes shaping the innovation landscape
  - EPSRC Future Manufacturing Research Hub (2017- 2023)
  - Training & studentships,
  - Capital & infrastructure
  - Basic, Applied and Translational Research Programmes
- 130 staff and rising : international talent
- Pre-competitive=leverage Portfolio of confidential projects
- Hub @ £100m Technology Innovation Centre @ Strathclyde
- 7 Tier 1s:GSK, AZ, Novartis, Bayer, Takeda, Lilly, Roche
- 16 Tier 2 technology companies





### CMAC Continuous Manufacturing and Advanced Crystallisation

**Vision**: To deliver predictive design tools and novel integrated continuous processing platforms for the supply of next generation high performance personalised products.



#### **Academic Partners**









**Imperial College** London





#### **Supporters / End Users**













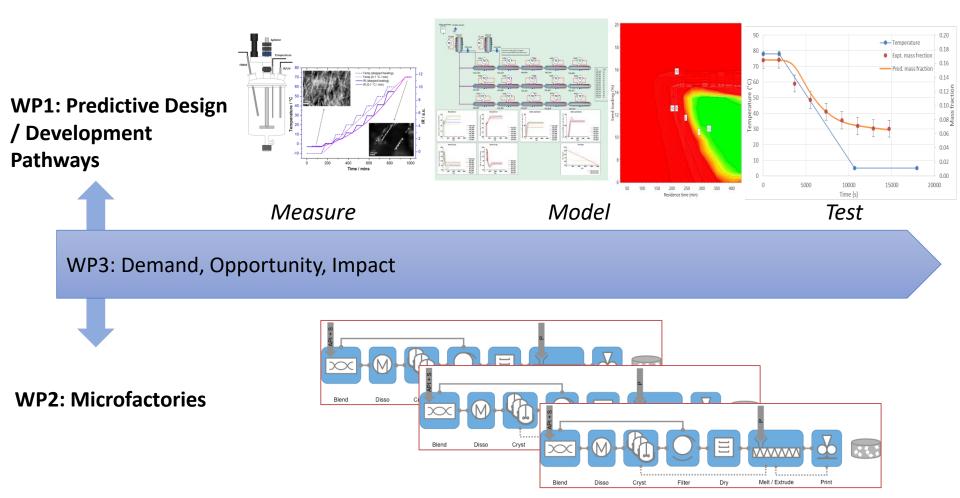






# **CMAC:** Predictive Process Design and Microfactory **Ecosystem**

- Develop using minimal material exploiting predictive modelling
- Control crystal attributes for enhanced manufacturability and performance
- Demonstrate simplified, integrated, flexible continuous process streams



Flexible, Modular, Integrated Platforms



### **CMAC Facility Supporting Access and Collaboration**

# Award Winning Facility for Continuous Manufacturing and Crystallisation Research





Process, PAT, Automation & Control, Analysis & Characterstaion



- Unique expertise in continuous crystallisation, process development, formulation and product analysis
- With continuous process skids for process development, state-of-the-art analysis and characterisation capabilities, comprehensive suite of PAT tools



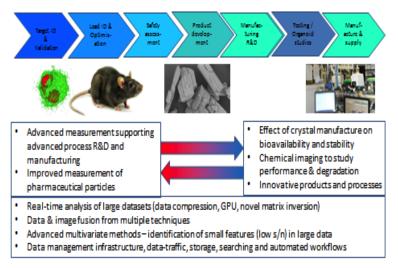
For more information contact national-facility@cmac.ac.uk



#### **Working Collaboratively**

#### CMAC and NPL

## Pharmaceutical Innovation and Manufacturing Metrologies Theme



NPL - Commercial

#### **Thematic areas**

- Data science challenges
- Novel in situ process analytical tools
- Measurement of composition, dynamics and structure in formulated systems

#### **MIT-CMAC**

### 2nd International Symposium on Continuous Manufacturing of Pharmaceuticals



Implementation, Technology & Regulatory
September 26–27, 2016

<b>Home</b> Agenda	SO, and HOI Copier Encipiert Solvent
Abstracts	B1 and B2
oster Session	
Vant to Attend?	N, and SOO, B4
Hotel Accommodations	Byproducts Additional
Conference Location	excipent Ar in
016 Regulatory White Paper	Copyright 2011 Noverta-MIT Center for Continuous Manufacturing
014 ISCMP Website	Schematic Vision of Continuous Manufacturing of Pharmaceuticals
-2014 CM White Papers  1 2014 Janet Woodcock, Head of CDER the FDA, has asked us to set up a ymposium to align on making ontinuous pharmaceutical manufacturing a reality Thus, we set up	Spring-boarding from our successful 1st International Symposium on Continuous Manufacturing of Pharmaceuticals (ISCMP), sponsored by CMAC and MIT (Novartis on May 27-28, 2014, we are planning a follow-up symposium, September 26-27, 2016, at the Royal Sonesta Hotel in Cambridge, MA, near MIT. This venue provides a pleasant and convenient site and allows us to expand the number of participants. As before, it will be by invitation only with the aim of getting representatives from a broad stakeholder comminity.
Instituted unity of the second	Based on feedback from the 2014 symposium, we plan to have a tangible output, with case studies, identification of technology gaps, proposals for addressing those gaps, and a draft document that can help inform future regulatory guidelines. We will form working groups with key stakeholders and post draft documents to the website to

- Community events in 2014, 2016
- Series of whitepapers output from 2014
- Regulatory whitepaper output from 2016
- Planning for an EU regulatory event 2017



### **I2APM**

International Institute for Advanced Pharmaceutical Manufacturing

Advancing the science and technology of integrated primary and secondary continuous manufacturing of pharmaceutical products





www.cmac.ac.uk