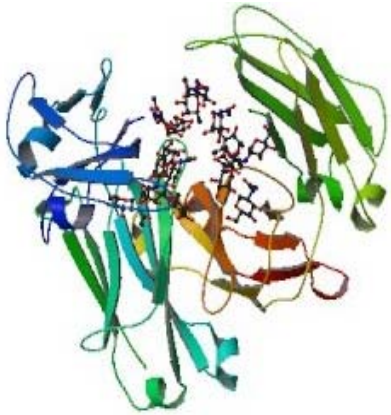
EPSRC Centre for Innovative Manufacturing in Emergent Macromolecular Therapies

Launch Meeting 17-18 November 2011

Creating manufacturing innovations so as to deliver affordable next generation advanced therapies to the UK healthcare system

Biopharmaceutical Lifecycle Optimisation



Complex macromolecular candidates

Optimise manufacturability and lifecycle costs

Affordable advanced therapies

Healthcare delivery to patient

Project Partners. Industry Associations: ABPI, BIA, HealthTech & Medicines KTN. **Companies:** Aegis Analytical, Avacta, BioPharm Services, BTG Plc, Eli Lilly, Francis BioPharma Consulting, Fujifilm Diosynth Biotechnologies, GE Healthcare, GlaxoSmithKline, Lonza Biologics, MedImmune, Merck & Co, MSD Biologics, Novo Nordisk, Novozymes Biopharma, Office of Health Economics (OHE), Pfizer, Syntaxin, The Automation Partnership (TAP), UCB Pharma. **Government-related:** Health Protection Agency, NIBSC, NHS QIPP.

The Objective of Today's Launch Event

- An opportunity to learn more about the challenges of the sector
- Keynotes selected to provide a breadth of vision as well as to set the backdrop to the Centre
- A chance to hear of our initial plans from each of the Centre investigators
- Outline of mechanisms for engagement
- Time to input to the Centre agenda and to help to shape the future

The Centre Academic Team

Prof. Nigel Titchener-Hooker (UCL Biochemical Engineering)
Centre Director

Leader of overall integration of Flagship Themes and Platform programme
Leader of ultra scale-down experimentation in Flagship 1.2

Dr Paul Dalby (UCL Biochemical Engineering)
Centre Associate Director

Leader of Flagship 1 on Rapid Determination of Manufacturability
Leader of biophysical characterisation of bulk product for manufacturability in Flagship 1.1

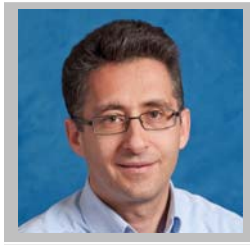
Dr Suzanne Farid (UCL Biochemical Engineering)
Centre Associate Director

Leader of Flagship 2 on Decisional Tools for Lifecycle Analysis
Leader of manufacturing cost modelling & lifecycle optimisation in Flagship 2.1 and 2.2

The Centre Academic Team

Prof. Steve Brocchini (London School of Pharmacy)
Co-Investigator

Leader of manufacturability assessment for formulation in Flagship 1.2



Dr Lazaros Papageorgiou (UCL Chemical Engineering)
Co-Investigator

Leader of cause-and-effect modelling & mathematical programming in Flagship 1.2 and 2.2

Prof. Steve Morris (UCL Epidemiology & Public Health)
Co-Investigator

Leader of healthcare delivery cost modelling in Flagship 2.1

Prof. Nina Thornhill (Imperial College Chemical Engineering)
Co-Investigator

Leader of multivariate analysis for facility fit prediction in Flagship 2.3

A Trio of Keynotes

- ***The cost dimension:***

  What's health economics got to do with it?

  Jon Sussex (OHE) and Stephen Morris (UCL)

- ***The international agenda:***

  Need for cost and time efficient commercialization of biotech therapeutics and technology drivers for achieving it

  Anurag Rathore (IIT Delhi)

- ***The role of innovation:***

  The Biochemical Engineering response to new markets, new regulations and new biology

  Barry Buckland (Biologics B)

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The EPSRC Centre for Innovative Manufacturing

Vision: To develop the tools and methods needed to enable more effective manufacture and delivery to the patient of potent new protein medicines at reduced cost to the NHS

Goals: Create techniques for early assessment of:

- cost-effectiveness
- ease of manufacture
- simplicity of delivery to patient

Conduct studies within a network of academics and users to extend the breadth of application and to deepen Centre capabilities

Establish the Centre as a national resource for manufacturing research, knowledge exchange and training in the sector

The EPSRC Centre

- *A collaboration initiated by an academic core*:-

  UCL – Biochemical Engineering (Lead)
  Chemical Engineering
  Health Economics
  ICL – Chemical Engineering
  LSoP – Formulation Engineering

- *Supported by a group of*:-

  25 industrial users including SMEs; with
  7 NGOs / Industry Associations

- *Extended by a network of*:-

  23 national & international academics

The EPSRC Centre – Basic Details

- ~£4.9m EPSRC
- ~£3.5m cash & in-kind
- 5 years duration; 38 FTEs; 6 PhDs
- 60% Flagship Research
- 40% Platform Enabling and Feasibility Studies

Flagship Projects

F1 Framework for rapid determination of manufacturability

F1.1 Biophysical characterisation of bulk product and final dosage formulations for manufacturability indices

F1.2 Cause-and effect models from microscale data

F2 Decision support tools for biomanufacturing lifecycle analysis

F2.1 Lifecycle cost evaluation tools: manufacturing through to the patient

F2.2 Integrated lifecycle optimisation and evaluation framework for complex macromolecular therapies

F2.3 Rapid prediction of facility fit issues upon transfer of optimal processes

Platform Element

- **Exploration:** Academic feasibility studies with external collaborators
  User demonstration projects

- **Networking:** Workshops, seminars, SIGs
  Website, database
  Showcase
  Overseen by *Network Group*

- **Impact:** Dissemination & Knowledge Transfer
  MBI / VISION for delivery
  Annual stakeholder events
  Secondments (two-way)
  Overseen by *Advisory Board*

Feasibility Studies

- A key mechanism by which the Centre will extend and prove its impact
- Objective is to use these studies in order to engage with individuals, groups and companies over time
- Centre has a series of routes for such studies; but this is work in progress **so your input is key**

  E.g.

  ⇒ 50:50 shared PhDs

  ⇒ PDRA secondment ***from*** Centre

  ⇒ PDRA / staff secondment ***to*** Centre
- We will use these studies strategically to build new grant bids and to enhance the sector capabilities

Feasibility Studies (Linked to Flagship)

- Biophysical measurement
  e.g. R. Curtis (Manchester) shared PhD

- New technologies and manufacturing strategies
  e.g. O.R. Thomas (Birmingham) shared PhD

- Modelling / Optimisation methodologies
  e.g. Sabbatical of Prof. Maravelias (University of Wisconsin)

- Lifecycle cost analysis
  e.g. A. Rathore (IIT Delhi) shared PhD

How to Access Feasibility Funds

- A word of caution! The Centre funds are limited so their use must be managed with care
- Our Advisory Board will help us to rank all bids for funds
- A proforma application is in your packs
- Deadline for expressions of interest: 23 January 2012
- Deadline for 2 page workplans: 1 May 2012
- Shortlisting and awards made: 1 July 2012

Criteria for Assessment of Feasibility Bids

- Innovation
- Relevance to Centre goals
- Potential for new collaborative grant proposals with Centre investigators
- Capabilities of the research group to deliver
- Level of commitment from the university

Feasibility Themes

Feasibility Theme 1: Biophysical Measurement

- **Core research will focus on:**
  - Establishing biophysical measurements that correlate to specific manufacturability issues for bulk products and final dosage forms.

- **Feasibility projects are welcome in relevant areas, including:**
  - Emerging techniques for biophysical analysis.
  - Computational modelling of protein structure and properties.
  - Assessment of new product types, formulations and delivery modes.

- **User Demonstration Projects:**
  - Specific assessment of biophysical methods on user specific molecules.
  - Use of additional biophysical techniques available at user sites.
  - Application to user specific process steps.

Feasibility Theme 2: New technologies and manufacturing strategies

- **Core research will focus on:**
  - Step change DSP operations or process materials and the introduction of novel manufacturing methods
- **Feasibility projects are welcome in the following areas, including:**
  - Novel adsorbent designs
  - Process integration
  - Continuous processing
  - Hybrid methods of manufacture
- **User Demonstration Projects:**
  - Testing the impact of new approaches in a real industrial setting
  - Evaluating new technologies with realistic feed materials

Feasibility Theme 3: Modelling / optimisation methodologies

- **Core research:**
  - Focuses on development of mathematical programming and evolutionary frameworks to optimise purification operations

- **Feasibility projects are welcome in the following areas, including:**
  - Predicting performance from process parameters and protein properties
  - Approaches for handling uncertainties during optimisation
  - Hybrid mathematical programming and heuristic solution algorithms
  - Statistical algorithms to analyse stochastic process datasets
  - Predictive models for novel chromatography resins/configurations

- **User Demonstration Projects:**
  - Test predictive correlations with user process data and proteins

Feasibility Theme 4: Lifecycle cost analyses

- **Core research will focus on:**
  - Generating tools to predict the cost of manufacture and the cost of treatment as a consequence of decisions made during manufacture and product design

- **Feasibility projects are welcome in the following areas, including:**
  - Contribution of manufacturing costs to overall drug price
  - Impact of mode of administration on health-related quality of life
  - Potential impact of value based pricing

- **User Demonstration Projects:**
  - How and to what extent is the cost-effectiveness of the final product considered at the manufacturing and product design stage?
  - Impact of process changes or reformulations on lifecycle management?

Networking Session

Feasibility Theme 1: Biophysical Measurement

Feasibility Theme 2: New technologies and manufacturing strategies

Feasibility Theme 3: Modelling / optimisation methodologies

Feasibility Theme 4: Lifecycle cost analyses

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