FIGSHARE
AT DE MONTFORT UNIVERSITY

Geoff Smith
Prof. of Pharmaceutical Process Analytical Technology

March 7th 2019 at the University of Leicester
The Projects

**LyoDEA**
Lyophilization process analytics
By dielectric analysis

**Biostart**
Biopharmaceutical Stability at Room Temperature

**AtlasBio**
Analytical Technologies for the Stabilization of Biopharmaceuticals

**FastLyo**
Formulation-Assisted Lyophilization by Reduced Vapour-Flow-Resistance

**EXTALcoat**
Process Design Excellence for External Tablet Lubrication Coating

The Vision

Scalable Process Analytical Technologies

Process characterization for scale up

- Product Temperature
- Drying Rates
- Kv and Rp
Biopharmaceutical Stability at Room Temperature

Analytical Technologies for the Stabilization of Biopharmaceuticals

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FastLyo
Formulation-Assisted
Lyophilization by Reduced Vapour-Flow-Resistance

Z-FDM
Through Vial Impedance Spectroscopy

TVIS-C
TVIS-NC
TVIS-Hydra

The Product “Range”
Biopharmaceutical Stability at Room Temperature

Analytical Technologies for the Stabilization of Biopharmaceuticals

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The Projects

The Partners

UK Gov Standards Agency, Catapult Centres, HEIs

Process Engineering

Instrumentation

Contract Research

Large pharma

Innovative SMEs

Engineering and Product Design
Laboratory Research

Datafiles (.csv, .dat, .z) 86 Mb
Excel 350 Mb
Power point presentations 200 Mb
MS Word reports 3 Mb
PhD thesis 15 Mb
Photos/videos 37 Mb

- conferences
- Technical/industry meetings
- Project Management meetings
- PhD reports
New Product Development

- software
- Laboratory Instrumentation
- Hardware designs (CAD)
- User guides/manuals (installation & use)
- White Papers/application notes
- Supply chain
- Co-developers
- End users/evaluators
- DMU IP/legal services

Raw data
Processed data
New knowledge
Organization using Projects

DMU Process Analytical Technologies

- I have three impedance technologies (TVIS, Z-FDM, Z-HTFS), one electrostatic powder flow technology (EPFS), and a number of laser based technologies (Laser Speckle, Quantum Eraser, Laser Absorption in freeze-drying).
- For each we have user guides for the equipment and how to process the results; and where there are no PhD students working on these (e.g. Ahmet’s laser technologies) we’d also have presentations and reports on the data we gather with these laser technologies.

One Project Folder for each of the technologies being developed by DMU.

- **TVIS (Through Vial Impedance Spectroscopy)**
  - This technology has been developed through various Innovate UK collaborative R&D projects and has led to the creation of a number of instruments
  - Each instrument Type should have its own *fileset* containing the SOP (in Word) for installation and testing of the system. There may be more than one SOP for each instrument with each pertaining to a different freeze-dryer in which it is installed.
    - DMU 5 channel TVIS system
    - Sciospec ISX5 TVIS system
    - Sciospec 5 channel TVIS system
    - DMU single channel non-contact system
  - There are also common components used in each system, such as cables, connectors, pass-through elements that could be stored and given open access so that our tests site adopter can access the relevant details for spare parts and systems development purposes

- **FDZM or iZFDM (Integrated Impedance Spectroscopy and Freeze-Drying Microscopy)**
- **Z-HTFS (Impedance enabled high throughput formulation screening)**
- **EPFS (Electrostatic Powder Flow Sensor)**
- **ILSI (Intelligent Laser Speckle Imaging)**
- **LyoLAS (Lyophilization Laser Absorption Spectroscopy)**
- **QMT (Quantum Measurement Technologies)**
External Collaborations

Project Collaboration (TVIS Installation at Chulalongkorn University, Bangkok, Thailand)

This Project Collaboration has FIVE Filesets:

01 Project Funding
Internal or external grant applications, inc. travel grants

02 Legal
  Collaboration agreement (CA)
  Non-disclosure Agreement (NDA)
  Material Transfer agreements (MTA)

03 Standard Operating Procedures (SOP)
  SOP for hardware and software installation
  SOP for the use of the instrument
  SOP for data processing protocols
  Excel templates for data presentation and analysis

04 Validation Tests and Calibration Data
  (subject to company policy)
  Each data file should be named according:
  VAL001_YYYY/MM/DD_short description

05 Experimental Data (subject to company policy)
  Each data file should be named according:
  EXP001_YYYY/MM/DD_short description

06 Promotion and dissemination
  Photographs of site visits
  Emails authorising use of photos
One Project for each PhD student (Privileges: student and supervisors - RW)

Filesets for:

- Student Profile and Project Summary
- DMU documentation
  - Registration document (Word)
  - Annual Reviews (One PowerPoint report for each annual review (with the annual review date on the first slide)
  - Formal Review (MPhil /PhD transfer): Report (Word); Report (Power Point)
- Experimental
  - To be organised into sub folders (one per experiment)
  - Format for the title of the folder: 2019-02-01 short title
  - Example: 2019-02-01 TVIS study of the freeze-drying of sucrose/NaCl solutions
  - Each experimental fileset should include:
    - a copy of the experimental protocol (in power point with images of the experimental set up)
    - raw data files and images
    - processed data (e.g. Excel Workbook with data and figures)
  - There should be links to the copies of any SOP for the experiment and/or data processing routines (located elsewhere on Figshare)
- Reports
  - Literature Reviews (Report in Word to form the basis of the introductions to your formal review, your annual review and your thesis)
  - Interim reports, e.g. Power point presentations and Word documents (do not include your annual review or formal review documents here)
- Publications and Conference Presentations (to be in Projects folders for conferences and publications)
  - One fileset for each conference presentation
  - One fileset for each publication
- Thesis
  - Word document
Externally Funded Collaborative R&D Projects
One for each of the collaborative R&D projects being funded by external parties

- These projects have their own set of documents, which can be separated into
  - pre-start documentation,
    - the grant application and annexes; the supporting documents such as the collaboration agreement, financial plan
  - post-start documentation,
    - quarterly progress reports (folders named Q1 Report, Q2 Report etc., each containing the minutes of meetings and the quarterly progress report – usually a power point presentation) etc.

- LyoDEA
- Biostart
- AtlasBio
- EXTALcoat
- FASTlyo
Examples to date
Conference presentation

Generate private link
https://dmu.figshare.com/s/b279b67ab421a5e5e5e8ea
Product Design

Project Grant (Innovate UK 04 FastLyo)

20.2.2019 05:09
Micron Design