CCTech
CUBE CLEANTECH

DELIVERING ENVIRONMENTS FOR SCIENCE

BIOMEDICAL

GMP

CONTAINMENT

CCTech Staff – Meet Some of The Team

Fintan Lyons – Operations Director

As Operations Director, Fintan oversees all operational aspects of CCTech, ensuring that our strategic goals are met efficiently and effectively. By directing and coordinating production, supply chain, and distribution activities, Fintan ensures that our operations run smoothly and meet our client's high standards.

Heather Nash – Office Manager

Heather oversees the company's quality compliance accreditations and QMS which are crucial to our daily operations. These certifications and achievements instil a strong sense of confidence in our clients and collaborators, affirming that CCTech are an excellent business partner.

Kirsty Alder – GMP Document Controller

Kirsty manages our GMP document control system, ensuring all documents are accurate, up-to-date, and easily accessible. By overseeing the creation, review, approval, & distribution of critical documents, Kirsty plays a key role in maintaining our compliance with industry regulations.

Theodore Hutchings – Validation Officer

Theodore ensures that all our processes, equipment, & systems meet the highest standards of quality and compliance. By developing and implementing validation protocols, and overseeing the validation lifecycle, Theodore plays a crucial role in maintaining our regulatory compliance.

BIOMEDICAL GMP CONTAINMENT

Steven Cubitt

Managing Director

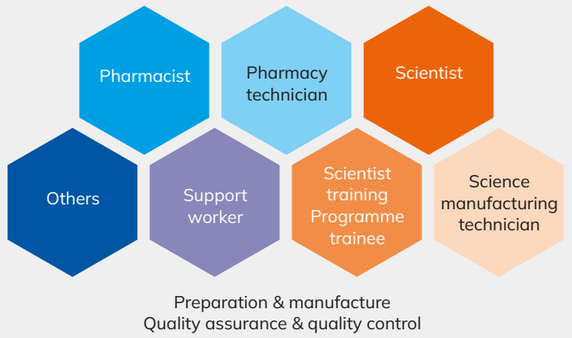
MSc, FIAT, R AnTech

40+ years of experience

Steven supports our clients in their specialist science and healthcare projects with the support of the CCTech team. Our roles on projects include Technical Advisor, Biomedical Consultant, Containment Specialist, Validation Lead, and Document Controller. CCTech forms a team around the client's requirements and supports our clients in taking their projects from feasibility to fully operational, using our team's skillsets to de-risk the project process. Steven has worked globally and brings that experience to each of our clients' projects.

"Our philosophy is to deliver facilities that meet the needs of clients and users, fully considering welfare and compliance with the relevant guidelines and regulations. We are currently working on a range of specialist projects including Polar Research, Tree Pathogen Research, Specialist Biomedical Projects, Specialist Cleanrooms for Process Gases & Healthcare, in both GMP and Containment."

Speak to me about regional hub projects at **steven@cctech.eu**



3.4 million individual doses prepared in English hospitals annually

£3.84 billion spent on injectable medicines across the NHS in England per year

We are supporting our NHS clients in the development of several Regional Hub projects to achieve the following national objectives:

Scaling up national production

The new hubs aim to significantly increase the production of injectable medicines, scaling up from the current 3.4 million individual doses prepared annually across hospitals in England to over 40 million doses to meet growing demand.

Improving quality and availability across England

By standardising and automating the production of 'ready-to-administer' batches, the hubs will enhance the quality and availability of medicines. This will positively impact patient care and support healthcare professionals involved.

Enhancing efficiency nationally

A network of Regional Hubs will produce high-volume products on an industrial scale using automated systems. This approach will free up nursing staff for patient care and allow hospital aseptic facilities to focus on more complex, individualised medicines for their local population.

Reducing medication errors

The transformation of the NHS aseptic service is expected to reduce medication errors by creating a more standardised and controlled environment for medicine production.

Investment in patient care

The development of hubs is an investment to improve patient care and deliver significant savings. Enhancing the UK's international status as an innovator in new medicines.

Support for complex medicines

Local hospital aseptic units will continue to make essential bespoke and complex medicines for individual patients, specific medical conditions, and clinical trials.

Pennie Soutar

Director GMP Projects

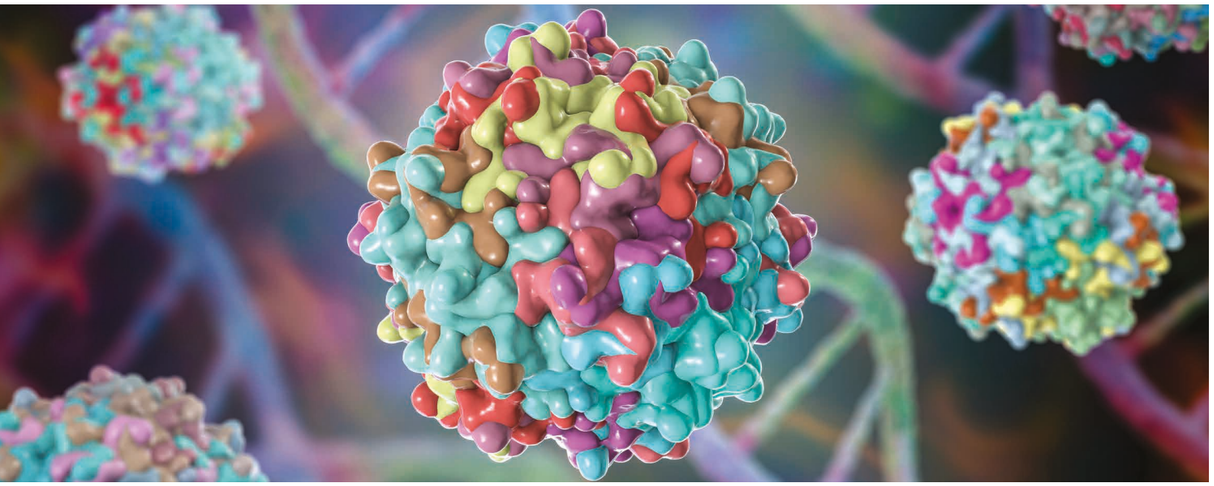
Biotechnology FDSC, Applied Science BSc (Hons), MRSB

20+ years of experience

Pennie oversees the GMP projects, providing specialist services on a wide range of projects in the UK, Europe, and Internationally. Pennie has over 20 years of practical and academic experience within the pharmaceutical and biotech industry, in a range of senior management roles from R&D, Technical, Operations, and Manufacturing within several well known companies and institutions including the NHS.

"We are at an exciting time for advanced therapy innovation. Various pharmaceutical & research companies are working on experimental therapies which have the potential to increase longevity & quality of life for many people. Healthcare delivery is constantly changing, with a focus on patient services, timely distribution and the latest GMP regulatory requirements."

Speak to me about GMP projects at **pennie.soutar@cctech.eu**



As of March 2024, there are now 14 advanced therapies approved and reimbursed in the UK, for diseases including specific forms of leukaemia, spinal muscular atrophy, and retinitis pigmentosa and over 2,000 are in clinical trials around the world.

At CCTech we support the feasibility assessment to accommodate the latest advanced therapies potential & innovation of our customers. Looking at the geographical impact, as well as the automation & process improvement that can be developed to maximise the capacity, flexibility and future-proofing of the Pharmacy Units. Using our wealth of experience on the regulatory requirements & manufacturing techniques & equipment, we support our customers projects from proof of concept to completed facility design, commissioning & validation.

What we can provide:

- Feasibility Study - proof of concept, predicted costs, support for OBC/FBC
- Procurement - specialist contractor and equipment
- Cross Contamination Control Strategies
- Cleanroom Design Review & Support
- GMP Procedural Developmen
- The latest Manufacturing Equipment Guidance including EMS & Isolator Technology
- Full Validation Lifecycle - including QTA, VMP, VP, URS, DQ, IQ, OQ, PQ
- Assistance with MHRA & regulatory audits

PROJECT

University Hospitals Plymouth (UHP) NHS Trust Regional Aseptic Hub

Background

University Hospitals Plymouth (UHP) NHS Trust, the largest Trust in the South West with over 1,000 beds, recognised the need for a modernised Pharmacy Aseptic Unit (PAU). The existing facility, at over 25 years old, was no longer fit for purpose. To address this, UHP embarked on a transformative project to establish a state-of-the-art Regional Aseptic Hub.

Project Scope

Project Scope: The Regional Aseptic Hub aims to provide a cutting edge PAU that meets the rigorous standards set by the Medicines and Healthcare Product Regulatory Agency (MHRA). The facility will specialise in the processing and production of aseptic prepared products, including:

- **CIVAS (Cytotoxic) Treatment:** The hub will prepare chemotherapy medications for cancer patients.
- **General Intravenous Preparations (IV):** A range of IV medications will be produced.
- **Parenteral Nutrition (PN):** Nutritional solutions for patients unable to take food orally.
- **Gene Therapy Products:** A dedicated suite will handle advanced gene therapies.

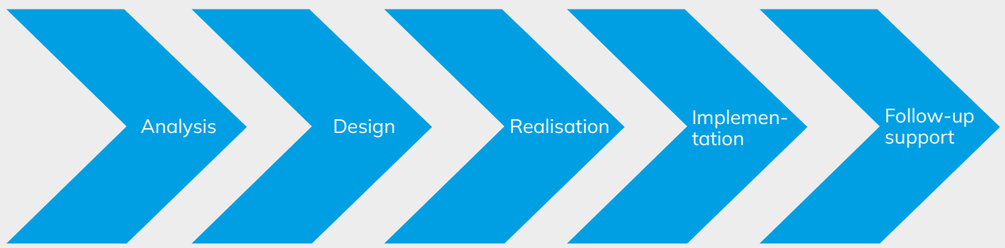
CCTech's Role

CCTech, as a trusted partner, both as Technical Advisor & Validation Consultant, oversees critical aspects of the project:

- GMP Facility Validation: Ensuring compliance in Classified and Controlled Not Classified (CNC) areas.
- User Requirement Specification (URS): Development of URSs for Facility, HVAC, EMS, & Isolator by actively collaborating with UHP End Users to define & document the specific requirements, ensuring alignment with clinical needs, safety standards, operational efficiency, and GMP regulations
- Validation Master Plan (VMP) and Validation Plans (VPs): Development of comprehensive VMP and VPs to outline the validation strategy and procedures to ensure compliance and reliability.
- Technical Advice: CCTech provided expertise during layout development and subsequent design stages ensuring the facility will achieve MHRA compliance.
- Procurement Support: Assist with Main Contractor & Specialist Subcontractor selection.
- Isolator and EMS Procurement: Facilitating the acquisition process.

The UHP Regional Aseptic Hub represents a significant leap forward in patient care, safety, and efficiency. By investing in this innovative facility, UHP reinforces its commitment to excellence and sets a benchmark for aseptic services in the region.

The validation phases



Steve Robertson Director of Containment

Chartered Chemistry (CChem), MRSC, MISTR, BERBOH, Cert Occ. Hygiene (includes P601 & 602 equivalent)

35+ years of experience

Steve is Director of Containment for CCTech, with over 35 years in Biocontainment & Chemistry laboratories. Steve has been actively involved in the design and validation of over 300 containment facilities throughout the UK and Ireland.

An Occupational Hygienist, Steven was responsible for the design & commissioning of research facilities for ICI/AstraZeneca/Syngenta, Steve also worked on the development of fume cupboard containment testing.

Steve sat on the BSI committees for BS EN14175 & BS7989 and provided input to BS EN 12469. He is a regular conference speaker on the design, validation, and fumigation of containment facilities.

Steve leads the CCTech Service Division which provides technical support, including inspection, test, and fumigation services for containment facilities across the UK.

Speak to me about containment projects at **steve.robertson@cctech.eu**

What the client says:

"CCTech have been involved as consultants from the initial design stages of the project all the way to validation and commissioning, they also hold the emergency fumigation contract for the facility for the next 12 months... CCTech have overseen all aspects of the proposed design, building by subcontractors, testing, validation and commissioning. In particular their expertise has been absolutely invaluable over the last 12 months of the project as the facility went through final construction and the critical stages of commission and validation. Their expertise and extensive experience have been invaluable in bringing a complex and ambitious project to the point where we had validated and functioning laboratories. I am also very pleased to now be working with them going forwards providing inspection and testing services as well as emergency formaldehyde fumigation cover.

In particular I have worked closely with Steve Robertson on the project and found him to be highly knowledgeable and effective at complex problem solving and driving the project forwards being an essential independent consultant from our contractors.

I do not hesitate to recommend CCTech, it has been a pleasure to work with such an effective company in such a specialist field. I would be happy to be contacted if you wish to discuss our experiences further."

Dr Mark Wills
Principal Investigator
Dept Biological Safety Officer
Chair University Biological Safety Committee

PROJECT

Jeffrey Cheah Biomedical Centre

Background

The Jeffrey Cheah Biomedical Centre is one of the largest Containment Level 3 (CL3) facilities in the UK. It comprises seven CL3 laboratories, including a flow cytometry laboratory, each access via it's own dedicated lobby and a number of support rooms.

Project Scope

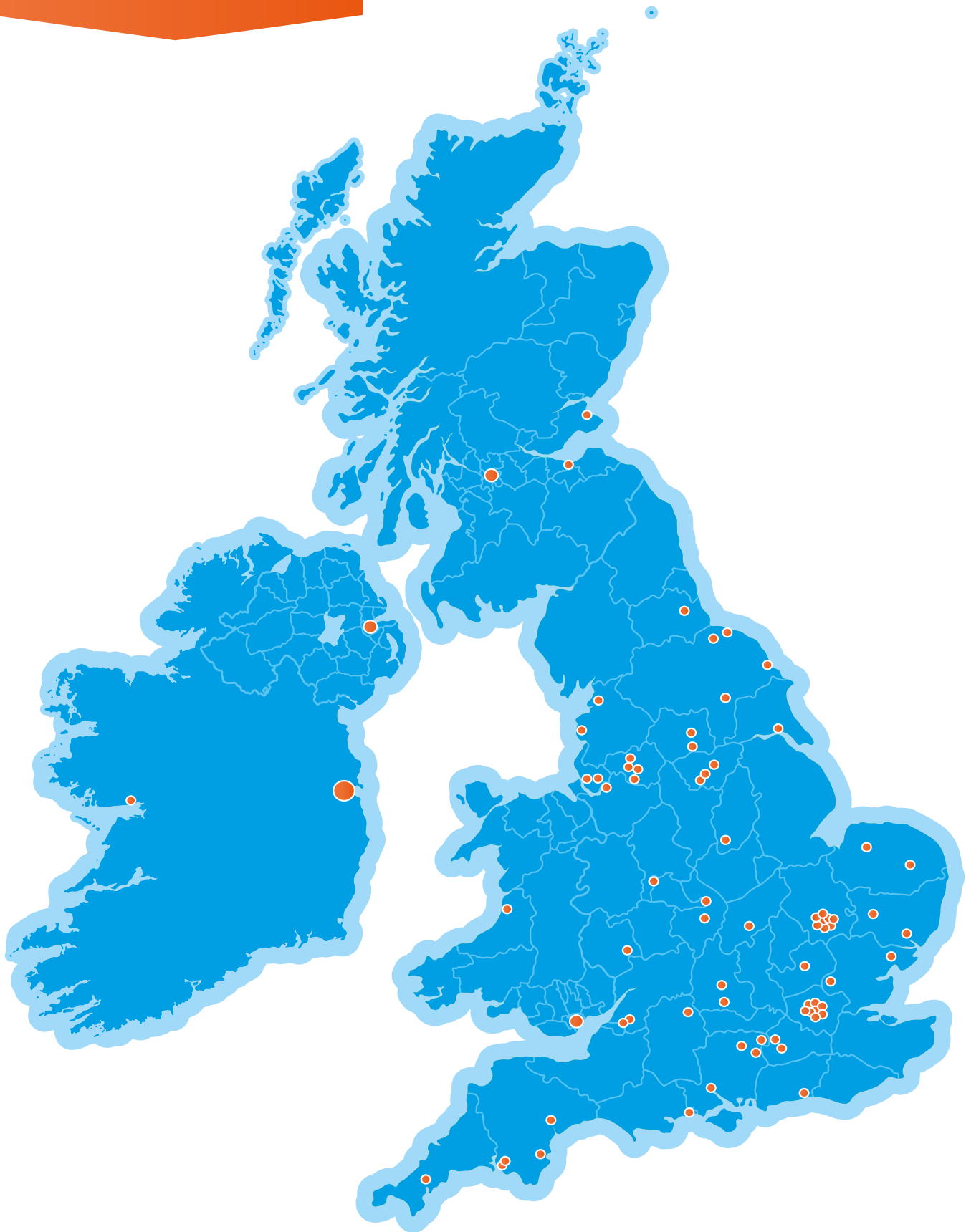
CCTech were instructed by the University of Cambridge to undertake a thorough validation of the facility, to ensure that it could be safely operated and fumigated, including under emergency conditions.

CCTech's Role

CCTech initially worked with the University of Cambridge to develop a comprehensive User Requirement Specification (URS). We also helped to develop operating procedures including emergency protocols and fumigation procedures.

- **Technical Advice:** Advice on the initial Design Qualification with ongoing support throughout detailed planning considerations and technical input.
- **Design Qualification (DQ):** Design Qualification preparation and execution to ensure that the facility met the requirements of the URS, regulatory standards, and emergency plans.
- **Validation Master Plan (VMP) and Validation Plans (VPs):** Production of a validation master plan to ensure all involved were fully aware of their roles and responsibilities as the laboratories were prepared for compliant operations.
- **Fumigation & Emergency Procedures:** Throughout the project, we identified the complex inter-relationships between laboratories within a shared suite and applied this to the fumigation strategy and emergency procedures for the operators.
- **Emergency Fumigation Services:** CCTech continue to support the facility through provision of emergency call-out fumigation services, annual inspections, and test for containment and sealability.

OUR PROJECTS



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