

CSL



2022 PhD Project opportunities

Are you interested in drug development? Do you want to shape future R&D for next-generation therapies? Want to gain experience working in a world-leading company?

- CSL, a world-leader in protein-based therapeutics, and UniSA have partnered to offer PhD projects, focusing on creating new approaches to support drug discovery and development.
- Successful applicants will gain expertise in mass spectrometry (MS) analytical methods for support protein-based therapy development.
- All projects have been designed so the applicant will spend significant time (up to 1/3 of the total project) on-site at CSL's state-of-the-art research facilities in Melbourne.

Project information

• There are 3x projects on developing analytical methods for automated and high-throughput characterisation of protein-based therapies. More info can be found <u>here</u>*.

What you end up with?

- Expertise in MS/proteomics, chromatography, protein characterisation
- Opportunity to translate your research and apply in real-word conditions
- Direct work expertise in the biopharmaceutical industry
- Opportunities to work with experts across Australia and overseas

Elgibility:

Domestic and international (already based in Australia) students are welcome to apply. Applicants must meet the eligibility requirements for a research degree program at the University of South Australia.

How to apply:

Apply online see link below. Please reference Supervisor: Professor Peter Hoffmann and your chosen project in your application. If you have any specific questions about the project(s) please email Professor Peter Hoffmann, <u>Peter.Hoffmann@unisa.edu.au</u>

Apply early to allow time to review your application and request any additional information required

https://workingatunisa.nga.net.au/cp/index.cfm?event=jobs.jati&returnToEvent=jobs.home&jobID=042A6679-047F-44A2-B3E4-ADBB0112F916&audienceTypeCode=UniSAHDRNoStyle&UseAudienceTypeLanguage=1



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Background

The use of monoclonal antibodies and recombinant versions of proteins as therapeutics, referred to as biologics, has changed the pharmaceutical landscape. It is anticipated that more than 70% of new drug approvals will be biologics by 2025, with seven of the ten best-selling treatments being protein based. The growth in protein-based therapies requires cutting-edge analytical tools to ensure the final product is of high quality, safe, and effective. CSL, a world-leader in protein-based therapeutics, continuously develops and adopts analytical strategies to support new research to better understand disease progression and identify new drug candidates. This involves investment into research on new analytics to provide important information for developing new therapies and ensure progression through the drug discovery pipeline. CSL, working with the University of South Australia and Karlsruhe Institute of Technology, have defined specific projects focused on creating new approaches to support drug discovery and development.

Project 1: Streamlined high-throughput analytical automation to support downstream process development and characterization studies

Objectives: Utilise novel and emerging at-line/on-line technologies to maximise sample throughput to provide comprehensive data set and faster assay turnaround to facilitate rapid downstream process development decision making.

Anticipated outcomes: A fully integrated automation stack with at-line/on-line analytics (*e.g.* protein concentration, impurities, aggregates, truncation, and charge variants) for high-throughput downstream purification screening support. Current CSL analytical throughput is not able to support design of experiment (DOE) type of downstream process development using robo-columns. This project will assess emerging new technologies that is able to deliver robust high-throughput analytical methods, for instance, ion mobility mass spectrometry (MS), chip-based impurity screening, size exclusion, dynamic light scattering, etc. The chosen analytical method will be inter- connected with Tecan robo-column by a mobile mechanic arm for at-line analysis. The developed automation platform will be of significant interest to all biopharma companies for rapid screening of different purification conditions, streamlining the Purification Process Development allowing the team to make informed forward processing decisions.

This PhD project will be in collaboration with CSL and up to 1/3 of the 3 years PhD project will be conducted at CSL's research facility in Parkville, Victoria.

Supervisory Team

Professor Peter Hoffman- Principal Supervisor

Dr Clifford Young- Co-Supervisor

Dr Chris Desire – Co-Supervisor

Dr Lucy Cao, CSL Innovation Pty Ltd – Associate Supervisor

Dr Matthias Zimmermann, CSL Innovation Pty Ltd – Industry Advisor







Project 2: PAT Spectroscopic and MS techniques for high throughput product characterisation for recombinant protein products

<u>Objectives:</u> Develop and establish a suitable process analytical toolbox (PAT) based on a combination of Highperformance liquid chromatography (HPLC), spectroscopy and mass spectrometry (MS)- based monitoring of critical quality attributes (CQAs) to drive process development for recombinant protein products.

<u>Anticipated outcomes:</u> From a regulatory standpoint it is important to assure that pharmaceutical processes are always controlled to ensure the therapeutic achieves a defined quality level. In biopharma, PAT has been recommended by the FDA since 2004 to manage production by monitoring and controlling processes to ensure a high-quality final product. PAT typically combines HPLC and spectroscopy data with chemometric analyses to obtain and analyse relevant information of the process and product quality, such as monitoring CQAs. By using PAT, critical decisions and process adjustments can be made in (near) real-time. The project will establish a high throughput and PAT suitable toolbox based on a combination of UV/Vis absorption, FTIR, MS and Raman spectroscopy for characterisation of CQAs. The approach will be specific for recombinantly expressed protein products, focusing on adoption of MS strategies, such as liquid chromatography (LC) coupled to high-resolution MS for monitoring quality attributes during production. Integration of MS data as part of a PAT requires a dedicated effort to ensure output is compiled in a way that can be incorporated and assessed in conjunction with other analytical strategies. High quality spectroscopic and MS data will be generated using potential therapeutic candidates provided by CSL.

Mechanistic models developed from the analytical approaches used will support the learning process of artificial neural networks (ANNs), to generate hybrid or meta-models for simplification of root cause investigations and improve process understanding. The project builds on expertise of Professor Hubbuch for PAT development, UniSA for spectroscopy, MS, and data analytics, and CSL for implementation to support recombinant protein products.

This PhD project will be in collaboration with CSL and up to 1/3 of the 3 years PhD project will be conducted at CSL's research facility in Parkville, Victoria.

Supervisory Team

Professor Peter Hoffman- Principal Supervisor

Dr Clifford Young - Co-Supervisor

Dr Chris Desire – Co-Supervisor

Professor David Beattie – Co-Supervisor

Professor Juergen Hubbuch, Karlsruhe Institute of Technology- Associate Supervisor

Dr Laura Cortes Castrillon, CSL Innovation Pty Ltd- Associate Supervisor

Dr Craig Kyngdon, CSL Innovation Pty Ltd - Industry Advisor







Project 3: PAT Spectroscopic and MS techniques for high throughput product characterisation for plasma derived products

Objectives: Develop and establish a suitable process analytical toolbox (PAT) based on a combination of Highperformance liquid chromatography (HPLC), spectroscopy and mass spectrometry (MS)- based monitoring of critical quality attributes (CQAs) to drive process development for plasma-derived protein products.

Anticipated outcomes: The project will establish a high throughput and PAT suitable toolbox based on a combination of UV/Vis absorption, FTIR, MS and Raman spectroscopy for characterisation of CQAs for plasma derived protein products. The approach will be specific for plasm-derived products, focusing on adoption of MS strategies, such as liquid chromatography (LC) Multiple Reaction Monitoring (MRM) MS quantitation strategy of proteins in human plasma fractions, to monitor plasma fractionation process performance. This integrated PAT approach will replace conventional biochemical approaches for targeted protein quantitation of plasma fractions. The data compiled from the mechanistic models developed from the analytical approaches used will support the learning process of artificial neural networks (ANNs), to generate hybrid or meta-models for simplification of root cause investigations and improve process understanding. The project builds on expertise of Professor Hubbuch for PAT development, UniSA for spectroscopy, MS, and data analytics, and CSL for implementation to support plasma-derived protein products.

This PhD project will be in collaboration with CSL and up to 1/3 of the 3 years PhD project will be conducted at CSL's research facility in Broadmeadows, Victoria.

Supervisory team

- Professor Peter Hoffman- Principal Supervisor
- Dr Clifford Young- Co-Supervisor
- Dr Chris Desire Co-Supervisor
- Professor David Beattie Co-Supervisor

Professor Juergen Hubbuch, Karlsruhe Institute of Technology – Associate Supervisor

Dr Supavadee Amatayakul-Chantler, CSL Behring Pty Ltd – Associate Supervisor

Dr Matthias Zimmermann, CSL Innovation Pty Ltd – Industry Advisor

Financial Support

These three projects are funded for reasonable research expenses. Additionally, a living allowance scholarship of \$28,597 per annum is available to eligible applicants. A fee-offset or waiver for the standard term of the program is also included. For full terms and benefits of the scholarship please refer to our scholarship information for <u>domestic students</u> or <u>international students</u>.

An additional top-up scholarship with a value of \$5,000 per annum will be offered to the preferred applicant.

For the application process follow the link below:

https://workingatunisa.nga.net.au/cp/index.cfm?event=jobs.jati&returnToEvent=jobs.home&jobID=042A6679-047F-44A2-B3E4-ADBB0112F916&audienceTypeCode=UniSAHDRNoStyle&UseAudienceTypeLanguage=1