

Job Description

Job title Innovation Lead – Materials Processing and Prototype Production

Faculty/Directorate: HLS

Grade: F/34 (Externally funded – UKRI)

Role profile: Research Assistant R1

Leadership and Management Level: N/A

Part time (50% FTE)

Fixed term (31.07.27)

	Duties of the role
Overall purpose of the role	Provide expert leadership for Chromar's formulation development, materials processing and prototype manufacturing activities. The role will oversee the development of materials and formulations according to Chromar's intended usages, manufacture prototype products, undertake routine process and product checks, and maintain accurate manufacturing and experimental records. The postholder will work closely with Chromar's research and commercial teams, external technical and regulatory partners, and project personnel to translate laboratory formulations into reproducible prototype formats, including powders, gels and other delivery formats. The role will also provide technical leadership and supervision for project students and other personnel undertaking formulation, materials processing, characterisation and prototype development.
Main duties and responsibilities	• Lead on Chromar's laboratory and prototype manufacturing work, working pharmaceutical equipment in accordance with approved SOPs, risk assessments and operating procedures. Specifically, and predominantly relating to electrospinning and large format batch processing equipment for powder synthesis. • Reporting line: Formally line managed by Chromar's CEO, the post holder will also report to Chromar's CSO. Outside of weekly meetings with CEO and CSO, independent decision-making powers are delegated in line with operational efficiencies; formulation adjustments or strategies would require approval; facilitative decisions around working with those formulations are delegated to the postholder. • Support the installation, commissioning and routine operation of new and existing equipment. Assist with equipment qualification, validation activities, calibration checks and preparation of associated records where needed as directed by CEO and CSO. • Prepare/adapt raw materials, formulations and biomaterial components

Duties of the role

according to approved experimental and manufacturing protocols in accordance with products requirements approved by CEO and CSO.

- Manufacture and process Chromar prototype materials and products, including powder, gel and other prototype formats. Drive forward electrospinning, powder processing, filling, grinding and other relevant materials-processing activities to establish SOPs complementary to Chromar's product development aims.
- Carry out routine measurements and in-process checks to assess material and prototype consistency. Record manufacturing parameters, material quantities, equipment settings, observations and test results accurately and contemporaneously. Maintain batch records, equipment logs, cleaning records, material inventories and other technical documentation. Interpret routine and other findings, compare results against specifications or acceptance criteria, and identify out-of-tolerance results. Final sign offs of changes/adaptations to be approved by CEO and CSO.
- Define, draft and update SOPs, manufacturing protocols, experimental procedures and risk assessments. Identify and report equipment faults, process deviations, material inconsistencies and other technical issues to CEO and CSO and undertake initial diagnosis of equipment faults, process deviations and material inconsistencies; implement permitted corrective action and escalate complex or significant matters to CEO and CSO.
- Assist with laboratory organisation, equipment maintenance, cleaning and safe storage of materials and prototypes. Postholder has the delegated responsibility to cease activity, remove equipment from use, quarantine materials and escalate potential safety failures without the express direction/permission of CEO and CSO, although such issues are to be reported and discussed to find suitable resolutions long term.
- Ensure all work is conducted in accordance with relevant health and safety requirements, approved risk assessments and Chromar procedures.
- Support preparation of materials and prototypes for laboratory evaluation, collaborator testing and future end-user assessment. Maintain accurate manufacturing, equipment, batch and experimental records required to support regulatory and quality documentation. Formal record keeping and review responsibilities are delegated to the Postholder, with final sign off by CEO and CSO.
- At the direction of CEO and CSO, work with external regulatory, quality and technical partners to support Chromar's regulatory strategy and MHRA-related activities. Contribute technical evidence and documentation to MHRA registration activities and other regulatory requirements relevant to Chromar's intended product classification and route to market. Postholder will prepare documentation only, CEO and CSO own the regulatory strategy, product classification, submissions, communications with the MHRA and final sign-off.
- Ensure experimental and manufacturing records are complete, traceable and maintained in accordance with Chromar procedures and requirements defined by external regulatory and quality partners. Contribute to accurate

	Duties of the role
	record keeping required for technology development, quality assurance, intellectual property and future regulatory activities. Postholder is responsible for ensuring records are accurate, contemporaneous, complete and traceable for quality assurance, IP, and regulatory purposes. Final regulatory authority resides with CEO and CSO. • Provide technical supervision and technical direction to project students and junior personnel undertaking experimental pharmaceutical process research and manufacturing activities. Ensure that students and personnel working within the facility are appropriately trained in equipment operation, SOPs, risk controls and laboratory/manufacturing practices. • Postholder will recommend, not control budgets/expenditures for equipment, consumables, maintenance, calibration and external technical or regulatory services. • Contribute technical information to grant applications, technical reports, intellectual property development and commercialisation activities at the direction of CEO and CSO. • Physical and environmental demands: The role will involve an anticipated 25% FTE laboratory time (half of the postholder's time), involving some standing for prolonged periods but this is not compulsory and rest breaks are easily integrated into laboratory workflows of the post. The role involves hazard exposure from mechanical equipment usage in formulation production, also from electrospinning processes, where the implementation and maintenance of correct PPE and exclusion zones are the direct responsibility of the Postholder. Manual handling is envisaged in equipment installation and operation, and good lifting and handling practice training will be undertaken by the Postholder upon appointment as part of general university induction processes. Act in accordance with DMU Values: • Collaborative – Work together to achieve joint outcomes, understand how your work contributes to DMU, and be aware of your personal impact on others. • Compassionate – Be open, honest, and caring, work on a basis of trust, and hold yourself accountable for your actions. • Creative - Strive for better, challenge bureaucracy, explore digital solutions, and innovate creatively. • Community minded - Embrace alternative views, treat others with respect, and tackle inequalities. • Treat all DMU staff, students, contractors and visitors with dignity and respect. Provide a service that complies with the Equality Act 2010, eliminating unlawful discrimination, advancing equality of opportunity and fostering good relations with particular attention to the protected characteristics of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief (or none), sex and sexual orientation.

	Duties of the role
	All members of staff are responsible for their contribution to improved environmental performance and in reducing greenhouse gas emissions at DMU. It is therefore required that all members of staff are aware of how the Environmental Policy relates to their own role at the University. Staff conduct must reflect the values inherent in the Environmental Policy and where required staff must cooperate with environmental compliance and conformance requirements to help minimise our emissions to air, water and land. The postholder should have a positive attitude towards health and safety, and be aware of and comply with all health and safety policies for the university, as applicable. There will be a requirement to complete all mandatory health and safety training as deemed to be relevant for the position held. The postholder is expected to help maintain a safe working environment for staff, students and visitors by working closely with the local safety coordinator as required. Any accidents or dangerous incidents must be reported promptly through the university's reporting system.

Person Specification

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Area of responsibility	Requirements	Essential or desirable		*Method of assessment			
				A	I	T	D
Qualifications & Training	Degree or equivalent experience in pharmaceutical science, pharmaceuticals, chemical engineering, materials science, biomedical engineering or a related discipline.	Essential		✓			✓
	Practical experience of laboratory-based formulation, biomaterials, materials processing or pharmaceutical manufacturing. Degree of experience: minimum of 1 year post-graduate.	Essential		✓	✓		✓
Previous Work Experience	Practical experience of laboratory-based formulation, biomaterials, materials processing or pharmaceutical manufacturing, degree of experience to be in excess of 1-year post-graduate.	Essential		✓	✓		✓
	Experience of preparing SOPs, risk assessments, protocols and technical documentation.	Essential		✓	✓	✓	✓

Area of responsibility	Requirements	Essential or desirable		*Method of assessment			
				A	I	T	D
	Experience of working with regulatory or quality documentation, including MHRA-related activities.	Essential		✓	✓		✓
	Experience of supervising or providing technical guidance to students, researchers or laboratory personnel.	Essential		✓	✓		✓
	Experience of pharmaceutical, medical-device or biomaterials manufacturing environments.	Desirable		✓	✓		✓
Specific Knowledge/Skills /Abilities	Experience of equipment installation, commissioning, qualification, validation or technical troubleshooting.	Essential		✓	✓		✓
	Experience with electrospinning, formulations testing and optimisation, extrusion and materials processing technologies.	Desirable		✓	✓	✓	✓
	Knowledge of quality-by-design, process development, equipment qualification or technology-readiness progression.	Desirable		✓	✓		✓
	Experience of working with external regulatory consultants or technical partners.	Desirable		✓	✓		✓
	Experience of prototype development and translational research.	Desirable		✓	✓		✓

Area of responsibility	Requirements	Essential or desirable		*Method of assessment			
				A	I	T	D
	Ability to develop reproducible manufacturing and processing procedures and investigate process variability.	Essential		✓	✓		✓
Organisation	Strong organisational, documentation and problem-solving skills.	Essential		✓	✓		✓
Communication/ presentation skills	An experienced communicator of scientific findings to mixed audiences, capable of delivering updates, results, findings and problems in a timely and concise manner at regular intervals as required.	Essential		✓	✓	✓	✓
Motivation and attitude	Ability to work independently while coordinating effectively with multidisciplinary research, commercial and external partner teams.	Essential		✓	✓		✓
Other requirements	Excellent record keeping, time keeping and communication skills.	Essential		✓	✓		✓
	Living close to Leicester or ability to commute easily to campus to perform lab-based tasks when required.	Desirable		✓	✓		✓
Our Values and Behaviours at DMU							
Collaborative	Support colleagues to achieve outcomes whilst being aware of personal impact of individual contribution and impact on colleagues	Essential		✓	✓		
Compassionate	Act openly and honestly, showing care to others and holding oneself accountable for own actions	Essential		✓	✓		
Creative	Striving for better, offering constructive challenge to creatively explore solutions and innovations to improve	Essential		✓	✓		
Community-minded	Treating others with respect, demonstrating empathy and embracing alternative views and values whilst seeking to tackle inequalities	Essential		✓	✓		

Area of responsibility	Requirements	Essential or desirable		*Method of assessment			
				A	I	T	D
Our Values and Behaviours at DMU (if manager/leader)							
Collaborative	Foster team collaboration and the exchange of best practices, establish clear and ambitious goals, develop work plans focused on achieving outcomes, and identify and nurture individual strengths to support development	Essential		✓	✓		
Compassionate	Offer honest and constructive feedback, cultivate a secure and open workplace, make difficult decisions with credibility, and act with integrity and transparency	Essential		✓	✓		
Creative	Cultivate an environment that promotes questioning and idea sharing, minimises bureaucratic hurdles, encourages open dialogue about mistakes, and engages the teams in ongoing service improvement.	Essential		✓	✓		
Community-minded	Encourage diverse viewpoints, swiftly address conflicts and inappropriate behaviours, and nurture a culture of mutual respect.	Essential		✓	✓		

***A = Application Form; I = Interview; T = Test; D = Documentary Evidence**