

Head of GMP Operations - MMIC – Job Description

Role Purpose:

Provide operational and technical leadership and expertise, recruit and lead a multidisciplinary team accountable for the MMIC operations. Develop and coach the Operations team Leaders/Team members to deliver agreed programmes of work to required GMP standards. The Head of Operations will, through their knowledge of both Primary and Secondary manufacture, offer innovative solutions at business-unit level, contributing extensively to development and improvement activities. Identify and address future operational capability needs of MMIC and to build a team to deliver on the MMIC strategy.

Key Responsibilities:

- To maintain consistent and documented compliance with all relevant Safety, Health and Environmental (SHE), quality and best practice requirements.
- To effectively lead the MMIC GMP Operations team. Define goals and performance objectives, sharing and translating area strategy, ensuring identification and delivery of departmental goals, through utilisation of appropriate management styles, providing feedback and motivation to team members and enabling individuals to meet their potential. This includes providing strong managerial leadership, performance management, resource allocation and long-term planning to ensure the successful delivery of the both current and future Grand challenges.
- To undertake all Leadership activities to ensure the smooth running of the group. This will include:
 - Setting team and individual objectives to meet departmental, business unit, and company objectives, contributing to the wider strategy
 - To agree weekly workplans with team leaders/managers, project manager(s) and other relevant stakeholders, and ensuring delivery to agreed schedule Medium to long term forecasting and planning of activities and objectives
 - Identifying and conducting performance management activities to ensure behaviours and performance of team meet required expectations, providing training and/or relevant support where needed
 - To provide high quality strategic and budgetary input into the CPI budgeting process.
 - Act as a point of contact for team leaders/members' queries and escalations with regards to more complex matters
 - Establishing a performance management culture and management reporting structure, based on; KPI dashboard, one to one sessions and performance development conversations
 - Ensure high levels of communication, feedback and performance across team
- To provide the Business Unit Director and Executive Leadership team with operations and GMP technology advice and thought leadership.
- To form strong interdisciplinary links across teams to ensure seamless incorporation of operations and GMP science technology knowledge and tools at the appropriate point in project development.
- To utilise own expert knowledge to assist in translating business unit strategy into practice through the delivery of plans to set and achieve team and business unit objectives.
- To build, maintain and exploit a network of relevant external stakeholders, customers, partners, research organisations and authorities, to represent CPI and self as a credible expert, identifying opportunity for future projects and developments.
- To actively contribute to a culture of continuous capability development through coaching, mentoring

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and/or developing colleagues across the business unit and organisation, providing insights into areas of specialism.

- To develop and promote a strong commercial and customer focus culture within CPI's MMIC business.
- To working collaboratively with the BD team providing technology and industry knowledge support to shaping project propositions to help secure new business and facilitate project due diligence and de-risking.
- To lead due diligence in Operations, develop detailed understanding of client expectations and capability needs.
- To work closely with the client, project and programme delivery teams in order to predict, understand and interpret customer needs and meet requirements
- To keep self and team up to date with external developments in areas of specialism, and/or legislative and SHE related changes, ensuring implementation and application of new best practice and/or knowledge across the team.
- To actively engage in hazard studies / SRA studies and discussions, as appropriate to role level.
- To be accountable for providing clearly documented records of technical data, decisions, methodologies, calculations and software use in an agreed format.

Responsibilities specific to role

- Lead the team accountable for the cGMP manufacturing suites at CPI MMIC Glasgow and oversee the teams responsible for logistics and all production/manufacturing operations including Inbound and outbound materials, activities within the main GMP room and GMP utilities.
- Ensure the required quality and safety standards are achieved and maintained with respect to cGMP operating procedures, all cGMP batch manufacturing documentation, area housekeeping in cGMP suites, SHE (Safety, Health & Environment), and compliance with the relevant regulatory (ICH Guidelines, PIC/S, MHRA Orange Guide) and legislative requirements.
- Training of staff (internal or contract) operating in cGMP suites.
- Working with other groups for requirements relating to quality systems, safety, cGMP areas facility maintenance, cGMP related utilities maintenance & availability, equipment engineering & maintenance, validation, and warehousing for cGMP related materials /product storage.

Direct reports: Up to 10 direct reports

Education / Qualifications:

Essential:	Desirable:
Educated to HNC or Foundation Degree level (or equivalent) in a Scientific/Engineering discipline plus significant industrial experience at a senior level Or Educated to Degree level (or equivalent) in a Scientific/Engineering discipline plus relevant industrial experience at a senior level Or Educated to Master Degree level (or equivalent) plus significant industrial experience Or	Supervisory or Management qualification Chartered status with a relevant professional institution

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<p>Educated to PhD level (or equivalent) in a Scientific/Engineering discipline plus relevant industrial experience</p> <p>Successfully completed formalised management training / managerial development programme, or has equivalent experience</p>	
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Competencies and behaviours	
<p style="text-align: center;">Leadership (Guiding)</p> <ul style="list-style-type: none"> Leads people with confidence and is empathetic. Displays flexibility in leadership styles in order to tell/sell/involve and delegate. Empowers others to constantly achieve and strive to exceed personal and company objectives. Talks beyond today, about future possibilities optimistically, showing others how they can benefit and contribute to the business. 	<p style="text-align: center;">Decision Making (Guiding)</p> <ul style="list-style-type: none"> Confidently takes decisions that require political/organisational interpretation and that could cause controversy but moves CPI forward. Reliably and boldly takes decisions involving the charting of a way forward into a new territory where no precedent exists and analysis of all available data provides no clear single conclusion. Models drive and resilience in ensuring the solutions are adopted.
<p style="text-align: center;">Communication (Guiding)</p> <ul style="list-style-type: none"> Personally takes the lead in creating an environment that encourages open and honest communication at all levels in the organisation. Motivates and influences others via their communications. Adapts communication style and format recognising individuals' different needs/motivations. 	<p style="text-align: center;">Developing self and others (Guiding)</p> <ul style="list-style-type: none"> Intervenes to address sources of lagging performance. Provides challenging and stretching tasks and assignments to develop others. Highly effective at supporting high performers and addressing underperformance through effective, constructive and open dialogue. <p>Collects information on performance and evidence of behaviours, and uses it effectively to improve individual and team performance.</p>
<p style="text-align: center;">Collaboration (Guiding)</p> <ul style="list-style-type: none"> Displays a collaborative style in day-to-day working whilst motivating others to achieve optimal performance and results. Develops relationships which facilitate the resolution of complex tasks and can apply different techniques to effectively mitigate any conflict. Can negotiate skilfully in tough situations with all stakeholders. 	<p style="text-align: center;">Delivery (Guiding)</p> <ul style="list-style-type: none"> Demonstrates the ability to prepare, gain approval of, refine and update business cases that justify the initiation of a project. Displays the ability to manage stakeholders, taking account of their levels of influence and particular interests. Ensures actions and decisions within the team are aligned with CPI's priorities. <p>Anticipates how team objectives must adapt and stretch to respond to change.</p>

Knowledge and Experience:

Essential:	Desirable:
<p>Will possess significant, technical expertise in Pharmaceutical GMP Operations (with knowledge of both the Primary (API) and</p>	<p>Is an active member of a professional body, engaging with peers beyond CPI.</p>

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<p>Secondary operations), as well as a compelling evidence of complex technical problem solving.</p> <p>Demonstrates a successful track record of leading, inspiring and motivating high-performance operational development teams.</p> <p>Will exhibit professional mastery of principles and practices in Bio/Pharmaceutical GMP Operations gained through career to date in area of expertise.</p> <p>Can demonstrate evidence of building knowledge sharing and network building practice across teams and organisations to achieve desired results.</p> <p>Demonstrates evidence of significant experience of developing, maintaining effective client relationships within a operations and GMP technology environment</p> <p>Demonstrates examples of leading project teams delivering from design through to delivery within multi- disciplinary teams</p> <p>Actively demonstrates in-depth technical and theoretical knowledge in Bio/Pharmaceutical GMP Operations and can participate at high level in more than one area. Is viewed as an authority in at least one area by peers and managers.</p> <p>Is able to take responsibility for diverse or complex technical activities where it is necessary to use own initiative and judgement, implementing innovative solutions in business critical situations.</p> <p>Will have sound experience of supervising a group or team within a Bio/Pharmaceutical cGMP operational environment and experience of managing performance within the team</p>	<p>Experience of packaging and inspection & storage of cGMP manufactured products.</p> <p>Understanding of cGMP areas facility maintenance, cGMP related utilities maintenance, cGMP equipment engineering & maintenance, Validation, and warehousing for cGMP related materials /product storage.</p> <p>Experience in a business development or entrepreneurial environment</p> <p>Track record of holding senior process positions preferably in a pharmaceutical/CMO/manufacturing environment.</p>
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