

## Fill Finish Subject Matter Expert (SME)

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Company: PM Group

Location: Antwerpen

Category: computer-and-mathematical

**Overview** The Role The role is to work as a Subject Matter Expert providing technical leadership on Fill Finish. As a member of the global SME Group the person employed can be located in one of the PM Group offices in Ireland, UK, Belgium, The Netherlands or Poland. We work a hybrid work model while the role will require travel to project meetings/workshops as required. Who we are PM Group is an employee owned, international project delivery firm with a team of 3,500+ people. We are world leaders in the pharma, food, medtech and mission critical sectors. From our network of offices in Europe, Asia and the US, we work with the world's leading organisations. We are focused on growing a sustainable business centred around our people, our clients and trade partners.

**Responsibilities** To be a technology leader in nominated area(s) which includes: Being current in technical and subject knowledge Being aware of upcoming technology changes, developments, innovations Writing papers, presenting at industry conferences Being involved with industry bodies such as the ISPE, ICHEME, BioPhorum Promoting knowledge exchange within the company using appropriate forums, COPs, and teams To perform as an SME for the early project phases (i.e. ideally Site Master Planning, Feasibility, Concept and Basic Design phases). Typically this will include production and/or checking of early phase project deliverables appropriate to discipline speciality. This will include scoping and philosophy documents, production throughput analysis, process flow diagrams, equipment requirements, P&ID's and layout philosophies, early phase project reports. To technically assist project teams as required. To undertake Peer Reviews of work performed by other companies. To perform in appropriate SMEs reviews of client sites. To engage with global

network of SMEs and other staff and assist in the training and mentoring of the next generation of Subject Matter Experts in the company To participate and/or chair technical design reviews as appropriate To actively support and participate in PM Groups R&D Team (the TechTeam) and associated development and innovation activities. To support BD as required. This may include client visits, client pitches, proposal writing, and preparation of appropriate supporting materials. Travel to Project meetings /workshops as required Other special projects as assigned Specific Knowledge Areas to be covered by the Role include Principles of facility layout such as: Area classifications associated with the required process steps Layout adjacencies Segregation approaches Aspects related to unit operations and technologies such as: Small and Large volume parenterals Formulation Freeze/Thawing Filling and closing Lyophilisation Sterilisation and sanitisation Filling path Inspection Single use technology Component preparation and support areas Integrity testing CIP/SIP Clean Utility generation and distribution systems Waste systems Aspects related to equipment such as: Deep knowledge of various filling and closing equipment RABs & Isolators Lyophilisers Inspection equipment Packaging equipment Aspects related to facility operations such as: Operating philosophies Lean/Sigma Concepts Machine Efficiency (OEE) Contamination control GMP Regulatory framework, particularly Annex 1 and FDA Aspects related to project delivery such as: Basis of design Basis of safety Simulation tools Capacity calculations Tech Transfer Commissioning and Qualification Qualifications Bachelor's degree; Masters preferred 15 years+ of appropriate experience in design and/or operations and/or process development A history of wider industry engagement with institutions such as the ISPE and an awareness of key industry technology initiatives and direction Excellent knowledge relating to area of speciality A good understanding of the principles of facility layout and design as appropriate Good appreciation of appropriate Regulatory framework Good presentation skills and be comfortable client interfacing, facilitating workshops and technically assisting project teams. Have the ability to distil down problems to their essence, demonstrate problem solving ability, and have an ability to innovate.

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