POSITION PURPOSE
A brief summary of the purpose this position must fulfill.
Mylan Global Respiratory Group is building a team at our new facility in Dublin, Ireland, that will be responsible for pilot scale manufacturing, analytical testing and quality assurance of new inhalation drug products. The team will be part of Mylan’s Global R&D group with close links to commercial manufacturing.

Works in the Mylan Global Respiratory Group (MGRG) Pilot Plant on dry powder inhaler projects. Operates and maintains device assembly and packaging equipment in Mylan Global Respiratory Group Pilot Plant facility as directed by Device Assembly & Packaging Manager to deliver development and clinical supplies for Mylan’s dry powder inhaler (DPI) products. Works with other R&D colleagues on Dry Powder Inhalation (DPI) development projects across MGRG to execute product development activities and technical transfer of new products into the pilot plant in Dublin and subsequently into the Commercial Manufacturing Facility. Performs job functions in accordance with the local Environmental, Health and Safety guidelines. Ensures compliance with the Standard Operating Procedures (SOP’s) and adherence to current Good Manufacturing Practice (cGMP) requirements.

KEY SKILLS AND EXPERIENCE

• Experienced in the operation of bespoke automated and semi-automated engineering equipment for the assembly and packaging operations in a pharmaceutical or device R&D and/or a GMP manufacturing environment.

• Experience of device assembly and packaging development activities and operations for device systems in a GMP environment.

• Experience of GMP operations in a manufacturing environment including assurance that equipment, rooms, and personnel are set up appropriately for all clinical manufacturing and process development operations.

• Attention to detail related to documentation, writing, preparation and completion of R&D and GMP protocols, reports and batch documentation.

• Experience of working in a lean manufacturing environment.

• Experience in material management desirable.

ESSENTIAL DUTIES AND RESPONSIBILITIES
To perform this job successfully, an individual must satisfactorily perform each essential duty. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential duties.

• Assist in production of process development and clinical batches.

• Writing SOP’s, protocols and reports is essential for this position.

• Executes operations and unit processes for device assembly and packaging manufacturing campaigns. Responsible for cleaning of the area.

• Where appropriately trained or experienced, may be responsible for diagnostics of specific process equipment.
• Adherence to cGMP regulations/guidance.
• Attention to detail, ensure any issues are raised to the appropriate level within defined timelines.
• Organizational and planning skills and the ability to cooperate with others in a team environment will be critical to success.
• Assist in the creation, review of and execution against operational documents by providing input to the technical composition of the document (incl batch documents, validation and qualification protocols, log books, defect libraries.)
• Maintains working areas to be clear and free from hazards.
• Performs packaging, shipping and receiving function as required, including with external warehousing providers.
• Perform other duties as assigned.
• Available to work overtime when required.

QUALIFICATIONS
The qualifications listed below are representative of the minimum knowledge, skill, and/or ability required.

KNOWLEDGE
• A good understanding of device assembly and packaging operations in a device or pharmaceutical manufacturing environment.
• Practical experience of device assembly and packaging operations in a cGMP environment.

SKILLS AND ABILITIES
• Must possess good communication, time management and organizational skills.
• Proven team working skills.
• Ability to work within and maintain technical files provided by equipment suppliers.
• An ability to work flexibly in a changing environment and develop new skills.
• Microsoft Word and Microsoft Excel is desirable.
• Meeting goals/successful delivery.
• Understanding of safety and quality risk assessments.
• Proven track record in problem solving

SUPERVISION
This role does not include supervision of others and works under direct supervision.

EDUCATION/EXPERIENCE
Minimum of 3 years relevant experience is required in device assembly or on packing lines. However, a combination of experience and/or education will be taken into consideration.

LICENSES/CERTIFICATIONS
None required.

LANGUAGE SKILLS
Ability to read and interpret general business documents. Ability to write routine reports and general business correspondence. Ability to work with peers and communicate basic concepts.

**MATHEMATICAL SKILLS**

Ability to add, subtract, multiply and divide.

**REASONING ABILITY**

Ability to solve practical problems through standardized solutions that require limited judgment. Ability to follow prescribed and detailed procedures to solve routine problems.

**PHYSICAL DEMANDS**

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential duties of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform essential duties.

Intermittently sitting, standing, walking or stooping, may require significant periods of standing. Occasionally requiring to lift bulk containers of components, raw materials, work in progress samples or finished drug product in line with local manual handling assessments. Typically sitting at a desk or table for office based aspects of role (data entry, report writing etc.).

**WORK ENVIRONMENT**

The work environment characteristics described here are representative of those an employee encounters while performing the essential duties of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform essential duties.

Manufacturing environment.