

Qualified Person & Quality Assurance Manager " >

Job ID
326060BR
Nov 25, 2021
Italy

Job Description

Over 1000 associates at 31 sites in 12 countries currently make up Advanced Accelerator Applications. AAA is also an expanding business where we have the unique advantage to leverage the size and scale of Novartis, while working in a culture that is unbossed, curious and inspired – all to create impact for patients.

Release batches of pharmaceutical products for human use in accordance with the relevant requirements and the European Union pharmaceutical regulation (Directive 2001/83/EC for Medicinal products for human use).

Your key responsibilities:

Your responsibilities include, but are not limited to:

- Release the batches of radiopharmaceuticals produced according to Directive 2001/83/EC for Medicinal products for human use and National laws.
- Immediately communicate to competent authorities and to the person in charge of the company every substantial irregularity detected in the product that has already been placed on the market;
- Actively collaborate in the Competent Authorities inspections and effectuate the operations required by them; Supervise the general conditions of hygiene of the premises subject to its management;
- Contributing to the definition of production programs, ensuring their realization in quality, in time and in compliance with the Good Manufacturing Standards and current regulations;
- Certify the production operations on suitable documentation and have responsibility for their conservation/updating;
- Collaborate with the Quality Assurance department in maintaining the validation/qualification status of the production site, equipment, training of personnel and management of quality documentation. Collaborate with the Site Manager, the Quality Control Responsible and the Production Responsible for the definition of shifts and presence of production and QC personnel
- Work in shift with other QPs to supervise the production and quality control activities
- Is available for the assessment of OOS and deviations that occurs during the batch production and quality control

Diversity & Inclusion / EEO

Novartis si impegna a costruire un ambiente di lavoro eccellente e inclusivo e un team diversificato che rappresenti i pazienti e le comunità che serviamo.

Minimum Requirements

What you'll bring to the role:

- Education: Degree in Chemistry / Pharmaceutical Chemistry and Technology / Pharmacy
- Languages: Good knowledge of English
- Experience / Professional
- Ministerial Qualification as a Qualified Person.
- Experience in the radiopharmaceutical field or in a pharmaceutical company.

Why Advanced Accelerator Applications (AAA)?

Thousands of people die of cancer around the world every day. At Advanced Accelerator Applications (AAA), a Novartis company, our mission is to transform lives through radioligand therapy in nuclear medicine to fight several leading types of cancer. How will we continue to be on the cutting edge of medicine? We believe new groundbreaking solutions can be found at the intersection of medical science and digital innovation. That a diverse, equitable and inclusive environment inspires new ways of working. We believe our potential can thrive and grow in an unbossed culture underpinned by integrity, curiosity and flexibility. And we can reinvent what's possible, when we collaborate with courage to aggressively and ambitiously tackle the world's toughest medical challenges. Because the greatest risk in life, is the risk of never trying! Imagine what you could do here at Novartis!

Imagine what you could do at Novartis!

Commitment to Diversity & Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse team's representative of the patients and communities we serve.

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to learn more about Novartis and our career opportunities, join the Novartis Network here:

<https://talentnetwork.novartis.com/network>

Division

ONCOLOGY

Business Unit

ADVANCED ACCELERATOR APPLICATIONS

Location

Italy

Site

Colleretto Giacosa

Company / Legal Entity

AAA Italy Srl.

Job Type

Full Time

Employment Type

Tempo Indeterminato

Shift Work

No

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