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QA Validation Specialist - CATALENT

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Company: startpeople

Location: Belgium

Category: architecture-and-engineering

Description de fonction

Catalent Pharma Solutions is the leading global provider of advanced delivery technologies and development solutions for drugs, biologics and consumer health products. With over 80 years serving the industry, Catalent has proven expertise in providing development, production and packaging services for pharmaceutical and biotech companies. For the sterile production site located in Belgium in Brussels (Neder-Over-Heembeek) which is currently expanding its capabilities, we are currently looking for a**QA Validation Specialist.**

The Role :

The QA Validation Specialist :

Is acting as prime Quality contact for Manufacturing, Science & Technology, Process Validation, Engineering, CSV, Maintenance, and Metrology.

Is ensuring review and approval of equipment maintenance, calibration, validation, and qualification records

Is ensuring review and approval of cleaning validation and process validation records

Supports and approves investigations

Provides support during customer quality visits and audits

Reviews and approve equipment calibration, validation, and qualification records (URS, DQ, FAT, SAT, IQ, OQ, PQ, periodic qualification)

Provides QA support to NPI (New Product Introduction) projects and related validation activities

Provides QA support to Q&V (Qualification & Validation) projects and related validation

activities

Reviews and approves investigations for deviations, OOS related to validation activities

Provides support during customer quality visits and audits and during regulatory inspections

Profil

Scientific university degree (Pharmacist, Engineer, or equivalent)

Experience in working in a GMP environment

Experience of 3 years in a pharmaceutical / medical device environment in a quality role is preferred.

Fluent in English, good command of French

IT knowledge: MS Office (Word, Excel, Outlook), TrackWise

Knowledge of Quality Management Systems and relevant standards within the pharmaceutical industry: Eudralex – GMP; 21 CFR Parts 210 & 211

Specific knowledge of GMP regulations on Medical Devices: 21CFR Part 820, ISO 13485

Offre

What we offer is an exciting role, a chance to grow and learn new skills in a global company, and in the most challenging quality environment within the pharma industry – a sterile business

Potential for personal development within an international company

Defined career path and annual performance review and feedback process

Interesting salarial package

Meal Voucher, Eco Voucher ...

36 days’ holiday + bank holidays

Information

Catalent offre des opportunités enrichissantes pour faire avancer votre carrière! Rejoignez le leader mondial du développement et de la production de médicaments et aidez-nous à proposer plus de 7 000 produits qui sauvent et améliorent la vie des patients du monde entier. Catalent est une société internationale passionnante et en pleine croissance où les employés travaillent directement avec des sociétés pharmaceutiques, biopharmaceutiques et de santé grand public de toutes tailles pour faire progresser de nouveaux médicaments, du développement précoce aux essais cliniques et à la mise sur le marché. Catalent produit plus de 70 milliards de doses par an, et chacune sera utilisée par quelqu'un qui compte sur nous. Rejoignez-nous pour faire la différence !

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