Senior Design Assurance Engineer

Job Summary
This is your opportunity to use your design assurance skills and expertise in combination products and medical devices to support the delivery of our smart inhalation devices. This role will provide you with an exciting opportunity to work alongside industry experts and have a positive impact on patients' lives from around the world.

What you get
In return for your skills and expertise, we offer a competitive base salary, annual bonus and generous benefits package including a pension plan, life assurance, private health, dental plan, share save/incentive schemes, cycle to work scheme and free parking.

Requirements
We're seeking a talented design assurance engineer to support the development of our current and next generation of inhalation devices. You will play a critical role in ensuring our devices and combination products fulfil all requirements throughout the products' lifecycle.

Your key responsibility will be to verify our combination products and have overall responsibility for the design assurance process. This an exciting opportunity to use your design assurance expertise to ensure that our devices are safe and effective and meet their design requirements.

What you need
With a degree in a relevant discipline, you'll have a minimum of 5 years' experience in verification and validation of combination products and medical devices. You'll possess proven understanding of design assurance including excellent working knowledge of most or all of the below international standards and guidance.

- 21 CFR Part 820, QMS
- ISO 13485, QMS for Medical Devices
- Medical Devices Directive, 93/42/EEC → Medical Device Regulation (EU) 2017/745
    - Articles and annexes relating to CE-marking
- EN 60601, Electrical Safety
- BS EN ISO 20072:2013, Design Verification Testing
- ISO 27427:2014, Nebulising Systems
- EN 14971, Risk Management
- ISO EN DIN 10993, Biocompatibility

You'll be an excellent communicator and be proven to deliver accurate and concise outputs.

Preferred experience includes: human factors engineering / design validation; being audited by notified bodies, licensees, regulatory authorities; understanding of aerosol therapy of respiratory diseases.

About Vectura
It's an exciting time to join Vectura, as we execute our strategy to build a leading inhaled Contract Development and Manufacturing Organisation (CDMO) business.

We are a provider of innovative inhaled drug delivery solutions that enable partners to bring their medicines to patients. With differentiated proprietary technology and pharmaceutical development

expertise, Vectura is one of the few companies globally with the device, formulation and development capabilities to deliver a broad range of complex inhaled therapies.

We have ten key inhaled and eleven non-inhaled products marketed by partners with global royalty streams, and a diverse partnered portfolio of drugs in clinical development. Our partners include Hikma, Novartis, Sandoz (a division of Novartis AG), Mundipharma, Kyorin, GSK, Bayer, Chiesi, Almirall, and Tianjin KingYork.

Our culture has been created through the participation of our colleagues - a culture that encourages a diverse and inclusive workforce. We offer flexible working opportunities that promote a healthy work life balance. We nurture our people through vocational development, mentoring programmes and career development. You'll find this is an ideal place to develop a stimulating and rewarding career.

To apply
To find out more about the role and to apply online, click on the Apply button. For more information about Vectura and our products please visit our website www.vectura.com.

Before applying, please be advised to read Vectura's Privacy Policy by clicking on https://www.vectura.com/privacy-and-cookie-policy.