

Job Description

Job Title: Compliance and Quality Assurance Manager

Location: Bristol, UK

Reporting to: Head of Hardware (Person Responsible for Regulatory Compliance)

Contract: Permanent, 37.5 hours per week

The Company

Smartbox creates technology that gives a voice to people who don't have speech. Our products include a combination of specialist hardware, software and content and are used by people with disabilities across the world.

We are one of the leading companies in the field and pride ourselves on our innovative products and high levels of customer service. Everything we do is driven by a passion to improve the lives of people that use our technology.

At Smartbox we believe everyone has the right to a voice. This is what the company was founded upon nearly 20 years ago and remains true today. Our users represent a diverse community of individuals and we want to support them by promoting an inclusive culture within our team.

Smartbox operates out of offices in Great Malvern and Bristol in the UK, and in Pittsburgh in the USA. The wider Smartbox Group includes subsidiary companies in Germany (Rehavista) and the US (Talk to Me Technologies). In total, we are a team of around 500 people.

The Job

Smartbox requires a Compliance and Quality Assurance Manager to work within the product development team. You will be immediately efficient in compliance and regulatory process. You will have experience in a highly regulated and tightly controlled industry, such as the medical sector. You will take a hands-on approach, as well leveraging external resources to ensure conformity internationally.

Working with the new product development team and with our suppliers you will ensure conformity of our medical-grade tablet computers and accessories internationally. You will take ownership of the regulatory process, identifying legislation, applying standards, demonstrating conformity, compiling technical documentation, and declaring conformity.

You will be a driving force for quality in the development team. You will upgrade our team, systems and processes using innovative methodologies. Together we will achieve world-class levels of safety and reliability, cementing our reputation as the best in the industry.

Duties will include:

- Regulatory Compliance: Ensure that all products comply with local, national, and international regulations, including CE, MDR, FDA, FCC, RoHS, REACH, and other industry-specific standards.
- Documentation and Certification: Prepare and maintain all necessary documentation for product compliance, including test reports, declarations of conformity, and technical files. Liaise with third-party certification bodies as needed.
- Risk Management: Identify potential compliance risks throughout the product lifecycle and develop strategies to mitigate these risks.
- Testing and Validation: Oversee and coordinate product testing to ensure compliance with applicable standards. Work closely with internal and external laboratories to validate test results.
- Cross-functional collaboration: Collaborate with engineering, design, manufacturing, and legal teams to integrate compliance requirements into product development and manufacturing processes.
- Standards Development and Monitoring: Stay updated on changes to relevant regulations and standards. Participate in industry forums and standards development organisations.
- Training and Guidance: Provide compliance training and guidance to internal teams, ensuring that all stakeholders understand and adhere to regulatory requirements.
- Continuous Improvement: Lead initiatives to continuously improve compliance processes and systems within the organisation.
- Vigilance reporting.
- Field service notifications and field safety corrective actions.
- Raising and monitoring Hardware CAPAs/CCAR's & SCAR's.
- Other ad-hoc duties when required.

The successful applicant will also be asked to perform other duties on an ad-hoc basis and will need a proactive attitude to this.

Essential skills/attributes

- Degree or equivalent experience in an engineering discipline
- 4+ years' experience in product compliance or regulatory affairs
- A creative entrepreneurial attitude
- Infusing enthusiasm and a positive attitude into your work
- Expertise in Regulatory Process
- Proficiency in Quality Management Systems
- Technical Proficiency in Electrical Safety, EMC, and Environmental

- Effective Communication at All Levels: Demonstrating the ability to communicate clearly and persuasively across various organizational levels, facilitating effective collaboration and understanding
- 8D/CAPA
- High Level of Technical Skills
- Analytical Thinker: Demonstrating strong analytical thinking capabilities, enabling the navigation of complex risk determinations and the formulation of informed decisions based on critical analysis.
- Attention to Detail: Displaying a keen eye for detail and meticulousness in work, ensuring accuracy and precision in tasks and deliverables.
- Self-Starter
- Excellent Collaborative Skills
- Meticulous Organization
- Strong Project Management Skills: Possessing the ability to manage multiple projects simultaneously, ensuring timely delivery, effective resource allocation, and successful project outcomes.
- Global Perspective.

Useful skills/attributes

- Experience in a medical device company
- ISO 9001
- ISO 13485
- ISO 60601-1
- ISO 14971
- EU MDR
- FDA Medical Devices

Additional Information

- In this role, you will have the flexibility to work between your home and our office locations in Malvern and Bristol. For this role, we require the candidate to work in the Bristol office twice a week as a minimum.
- You will need to maintain a deep understanding and knowledge of all our products and their uses.
- You will meet and keep in regular contact with other teams in the business.

Rewards and benefits

Smartbox offers comprehensive benefits including:

- Company Pension.
- Group Life Assurance.
- Income Protection.
- Private Medical Insurance.
- 25 days holiday plus public holidays.
- Flexible working.
- Cycle scheme.
- Office snacks.
- Benefit and Wellbeing app Yulife with store discounts and wellbeing services available.
- Annual Charity Day.
- Long Service Award.
- Training and development opportunities.
- Complimentary theatre and cinema tickets to Malvern Theatres.
- EV car scheme through salary sacrifice after 2 years' service.
- Corporate gym membership discount.
- We are passionate about our people and offer many social events including team outings and get-togethers.

How to apply

We welcome applications from all communities and those from diverse backgrounds and groups. Please outline your experience and ability to excel in this role within your cover letter.

Diversity & Inclusion

We are proud to be a Disability Confident Employer and one of the sponsors for Purple Tuesday- the #1 brand working to improve the experiences of disabled people as customers 365 days a year. We are fully committed to the employment and career development of disabled people. To ensure everyone has an equal chance, we're always willing to make reasonable adjustments to the recruitment process. Should you require further assistance or require any reasonable adjustments to be put in place to better support your application process, please do not hesitate to contact us via email: jobs@thinksmartbox.com.

Smartbox

Communication is life

Corporate responsibility

At our company, we are driven by a passion for making a positive impact on society, minimizing our environmental footprint, and meeting the needs of our stakeholders. We have been actively working towards becoming B-Corp certified, aligning ourselves with a global movement dedicated to eradicating poverty, protecting the planet, and fostering lasting prosperity for all. To learn more about our commitment to sustainability, please visit this link: [Corporate Responsibility and Sustainability](#)