castor

Job Description

Director of Quality and Compliance

Department:	Operations
Type:	Permanent
Location:	Amsterdam or Remote
Hours:	32 - 40 per week
Reports to:	COO
Salary:	Competitive plus bonus and stock options
Posted:	September 2020

Our Core Values

Achieve anything with a healthy and happy team

Push boundaries through direct communication and diversity

Act responsibly and protect the data

Amaze through user-friendly and rewarding experiences

Maximize research impact

About the role

At Castor, we're all committed to a world with faster, smarter, medical research. Our cloud based software solutions are revolutionizing data capture for academic and commercial researchers worldwide. You've found yourself a company with a true purpose.

Our Operations team support all the professional 'cogs' that allow us to make the magic happen. As we move into our next investment, we're on the lookout for a Director of Quality and Compliance to join the team.

In this role, you'll take overall ownership and accountability for the entire Quality & Information Security Management (QISMS) system at Castor. By proactively managing quality and compliance , you'll keep the business ahead with requirements as we enter new, more regulated markets.

What you'll be doing

- Maintain a world-class QISMS that supports business needs
- Maintain Standard Operating Procedures and Work Instructions
- Ensure policies and procedures are lean and practical
- Educating teams on applicable regulations such as 21 CFR Part 11, GCP, Annex 11, GAMP, various relevant ISOs, and HIPAA
- Coordinate and conduct supplier audits
- Address QISMS gaps as we enter new markets
- Ensuring we are ahead of product compliance for new functionality
- Inform the product roadmap based on compliance gaps
- Support commercial growth through compliance documentation, RFPs, customer conversations and general sales queries
- Facilitate and coordinate customer audits
- Set up tooling to enable remote audits by prospects/customers
- Support market growth decisions based on compliance requirements

What you'll bring

You'll definitely have:

- Experience working in life sciences space with a strong understanding of Good Clinical Practice and 21 CFR Part 11
- Working knowledge of general quality and compliance principles
- Tech savviness with experience working in an IT/ technical environment
- A broad ability and passion for autonomy in a hands-on role
- The ability to communicate and drive decisions with Senior Managers
- A customer focussed and collaborative approach
- Exceptional written communication skills (eg - for SOPs)
- A pragmatic approach with an aptitude for process perfection
- The adaptability and resilience to thrive in a fast-paced startup

It would be good if you had:

- Experience of handling and answering compliance questions in RFPs
- eClinical technology platform experience (EDC, CTMS, eTMF, IRT)
- Certified Information Systems Auditor or Certified Quality Auditor (CQA)

Your main contact for this vacancy:

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