Regulatory Affairs Manager

Competitive Salary £65,000 + (depending on experience)

Introduction

The British In Vitro Diagnostics Association represents and advocates for the in vitro diagnostic (IVD) industry in the UK. We are seeking a Regulatory Affairs Manager to join us to support our nearly 250 members with regulatory affairs activity.

Who we are

BIVDA are the leading trade association for IVD's in the UK. Operating since 1992. We work with politicians and policy makers, government bodies and the NHS, to ensure that the UK diagnostic market is innovative, accessible, and meets the needs of patients.

This is an exciting time to join BIVDA, with a dynamic, stable, and supportive team, a new three-year strategy, and real ambition to expand our activities.

Who we are looking for

This Regulatory Affairs role is to help deliver the strategic objectives of BIVDA and BIVDA members by providing regulatory support activities and insights across the wider regulatory environment in the UK and internationally. You will be able to work independently and flexibly, identifying opportunities and challenges to which BIVDA will contribute and address. You will work closely with our Head of Regulatory Strategy, and the senior leadership team to shape the regulatory environment for Diagnostics.

You will have responsibility for BIVDA's briefings on regulatory affairs, to include key messaging, thought leadership, publications, consultation responses and policy positions. This role will lead BIVDA interactions with stakeholders and members.

You'll be involved in BIVDA's MHRA activity, and liaise with DHSC, UKHSA, Health Innovation Networks, Health Research Centres, and more, and you'll work on our Springboard programme mentoring new businesses with fantastic innovations and work with government for export and domestic growth.

The ideal candidate will need a good knowledge of the UK health sciences environment. Experience in the diagnostic industry, the NHS (including ISO standards and environmental regulations), and other health areas of the UK government would be advantageous. Regulatory qualifications (eg. TOPRA) and experience of internal quality management systems would be a real bonus.

There is the need for some travel to members and events, so you'll be willing to get out and see people, acting as an ambassador for BIVDA and showcasing our activities and talent.

What we offer

You'll be working with a passionate team of experts who take pride in the health benefits we deliver across the UK. This is a hybrid role – you'll need to visit members and attend our offices (less than a

minute from Oxford Circus underground station) and the Elizabeth Line (Bond Street) when required, but we encourage home working. We support our staff with private health care and an employee assistance programme. You'll enjoy a generous 25 days of annual leave, plus statutory bank holidays and three days leave at Christmas when our office closes. We also currently offer flexi-time, Time off In Lieu and Pension scheme.

Key Responsibilities:

- Represent members in advocacy for the regulatory environment in the UK, EU and ROW.
- Prepare briefings for the Chief Executive on matters of regulatory affairs and policy as the Voice of the Industry.
- Keep up to date with MHRA updates for all relevant regulatory subject areas.
- Develop and maintain stakeholder relationships with key MHRA, DHSC, HAS, DEFRA & DIT personnel.
- Monitor any new UK regulations / standards for IVDs and supporting BIVDA in summarising the new regulations / standards for BIVDA members.
- Maintain understanding of EU IVDR implementation progress to ensure that members are kept up to date in this key area.
- Chemicals - Provide information to BIVDA members regarding the UK REACH and EU REACH regulation as new information or guidance becomes available.
- Human Cells and Tissue Biologics – identify and understand new requirements and provide updates to BIVDA members regarding any regulatory changes in this area.
- Data Protection - Keep up to date of any changes regarding data protection both in EU and UK legislation. Monitor the Information Commissioner's Office's (ICO) website for developments for presentation to BIVDA members in an easy-to-follow format.
- Sustainability - Keep up to date of any changes regarding Sustainability or Environmental areas both in EU and UK legislation. Supporting the Head of Market Access, this will require regular review of any new requirements and presentation to BIVDA members in an easy-to-follow format.
- Main point of contact for regulatory affairs enquiries.
- Assist the Policy Officer with internal and external communications as required.
- Work with the working party chairs to ensure agenda issues are concluded.
- Support the Operations function with internal QMS.

Please send us your CV and a covering letter to helen.dent@bivda.org.uk or contact Helen for an informal discussion.

Closing date for applications is Friday 12th July 2024 at 14.00