Boulder iQ Innovation to Quality

Boulder Sterilization

Boulder iQ Bulletin

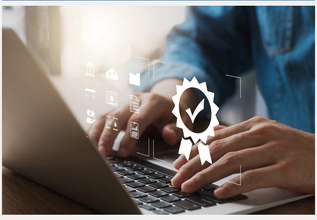
February 2023

REGULATORY AFFAIRS and QUALITY ASSURANCE

In this edition of the Boulder iQ Bulletin, we provide an overview of our regulatory affairs and quality assurance services, along with relevant articles.

- Boulder iQ Regulatory and Quality Services
- What is the Product's Intended Use?...a Simple Question With a Big Impact on the Success of Your Regulatory Strategy
- What Does the End of the COVID Public Health Emergency Mean for Emergency Use Authorizations?
- Past Articles

Boulder iQ Regulatory and Quality Services



Boulder iQ applies an engineering mind to regulatory and quality affairs, solving problems and creating value with a focus on detail and efficiency. From completing a short-term project to serving as an outsourced department, we provide the support developers need to get products to market and stay on the market.

All regulatory affairs and quality assurance services take place under one roof. For product developers, that eliminates the need to juggle multiple vendors, and simplifies project management and coordination.

FAQs
1. Getting my device to market hinges heavily on an effective and efficient regulatory strategy to make sure we obtain the necessary regulatory clearances and approvals. How can Boulder iQ ensure that my product will achieve clearance or approval as quickly as possible?
Boulder iQ offers complete, comprehensive regulatory affairs support, including:

- Regulatory strategy development
- FDA submissions: 510(k), IDE, PMA, De Novo
- FDA pre-submissions
- Request for Breakthrough Designations
- 513(g): Request for Classification
- EU MDR and IVDR: Complete transition planning and execution
- CE mark submission
- Clinical Evaluation Reports, technical documentation, Declarations of Conformity
- Post-market surveillance
- Remediation activities
- Audits: Internal, FDA QSR, MDSAP, pre-certification, pre-inspection, supplier, cGMP, clinical research study

Leading our team is Joanne Rupprecht, a highly experienced regulatory affairs advisor, federal agency/life sciences attorney and educator. Proficient in FDA and international regulatory affairs, and quality systems, she lends more than 35 years of healthcare product development experience to our clients, including the implementation of quality management systems and regulatory strategies, submissions and FDA negotiations for medical devices.

Our director of quality, Melinda Sopp, has two decades of experience in document control, quality assurance and operations. She has held managerial and executive positions in quality control, quality management, quality assurance and compliance, and has worked as a research scientist.

2. My device is far enough along that I'm ready for clinical trials. What kind of support can you offer there?
You can look to Boulder iQ's team for full support, starting with strategy and planning for your trial, as well as protocol development, full management of the trial and post-trial needs. We handle coordination with notified bodies, competent authorities, principal investigators, internal review boards and ethics committees, as well as international applications.

3. What areas of quality assurance do you cover?
Our experts can help with the full scope of services, starting with the development and implementation of ISO 13485-compliant Quality Management Systems. We offer process verification and validation, software security and validation, compliance for start-up companies and Corrective Action/Preventive Action (CAPA) matters. We also can perform quality system, ISO 13485, internal, gap, cGMP, supplier and clinical research study audits.

4. How can I be confident that I am in full quality compliance if working with Boulder iQ for my product development?
Boulder iQ implements its own Quality Management System – ISO-13485 certified and compliant with 21 CFR Part 820 – with clients. It's an easy-to-use system, and ensures that our clients achieve full compliance without extra work or worry.

What is the Product's Intended Use?...a Simple Question With a Big Impact on the Success of Your Regulatory Strategy

By Jo Rupprecht, Senior Vice President, Regulatory and Quality at Boulder iQ

The absolute path to a winning regulatory strategy is an Intended Use statement. Without a solid one – right out of the gate – anything you do will simply be a guess, and lead to wasted time and money.

The Intended Use Statement is simply an answer to the question, "What does the product do?" Creating the statement should not be difficult after all the feasibility work that most developers conduct. Yet it can be easy to get so caught up in technical details and the intricacies of the product development process that this top-level, guiding purpose can become lost.

READ FULL ARTICLE

What Does the End of the COVID Public Health Emergency Mean for Emergency Use Authorizations?

By Jo Rupprecht, Senior Vice President, Regulatory and Quality at Boulder iQ

I remember listening to many predictions after the Department of Health and Human Services (HHS) issued the COVID-19 public health emergency Jan. 31, 2020. None of them included that it would last for more than three years!

But the time has come. The federal government has announced that the COVID-19 public health emergency (PHE) is set to end May 11 this year.

So where does this leave the manufacturers of PPE, medical devices, diagnostic tests, therapeutics, and vaccines that commercialized products through EUAs?

READ FULL ARTICLE

PAST ARTICLES

How to Survive an FDA Inspection - Part 1
- Boulder IQ, November 1, 2021

How to Survive an FDA Inspection - Part 2
- Boulder IQ, November 15, 2021

FDA's Breakthrough Devices Program
- Boulder IQ, September 9, 2021

Boulder iQ is an expert contract consulting firm providing all the services life sciences companies need to get their products to market as quickly and efficiently as possible. We serve as a single source for device developers, providing full product development and regulatory services under one roof.

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