

Boulder iQ Bulletin

March 2023

In this edition of the Boulder iQ Bulletin, get to know our new COO, Steve Seyer, read some helpful tips for effective audits, and learn how to get the most out of a Q-Sub meeting.

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Team Member Spotlight: Steve Seyer



Meet Steve Seyer, our new chief operating officer. Steve is managing product development, manufacturing and sterilization, and leading efficiency enhancements in our processes and procedures.

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The Road to ISO 13485 Certification: Tips for Effective Audits



By Jo Rupprecht, Senior Vice President, Regulatory and Quality

Audits in your future? Joanne Rupprecht, Boulder iQ's senior vice president of regulatory and quality, explains how to prepare and eliminate fears in this new Med Device Online article.

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Med Device Online: February's Most Popular Articles



Last month, Med Device Online published a feature article by Jim Kasic, Chairman and Founder of Boulder iQ, titled, "**9 Key Investor Milestones Every Med Device Developer Should Know.**" And the topic must have caught the attention of MDO readers because it made the list of most popular articles for February!

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The Lure of the FDA Q-Sub Meeting - Part 1



By Jim Kasic, Founder and Chairman

The FDA's Pre-Submission Program, or Q-Sub for short, gives manufacturers of medical device and in vitro diagnostic devices a way to get feedback on the regulatory process and requirements for their devices. This article covers how to tell if – and when – to request a Q-Sub meeting, including whether to do one in Phase 0.

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The Lure of the FDA Q-Sub Meeting - Part 2



By Jim Kasic, Founder and Chairman

Part 2 covers strategic considerations for multiple Q-Sub meetings, how to structure and plan out the meeting, and choice of meeting spokesperson.

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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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