PINNACLE 21

http://www.pinnacle21.com
careers@pinnacle21.com

Pinnacle 21 is an established startup that builds software to streamline the drug approval process, bringing life-saving medicines to patients faster.

CDISC Implementation Consultant

As a member of the Consultative Services team, you will be responsible for educating and consulting internal and external Pinnacle 21 customers on the in's outs of both our product as well as its implementation and use within Clinical Trials. You will also leverage your domain knowledge and experience in our space to support this multi-disciplinary organization in many areas ranging from product development to customer success and support to thought leadership.

What you'll be doing

Provide consultative services to P21 clients

- By helping them with implementation of CDISC standards including SDTM mapping, analysis datasets specifications, creation of Define.xml files, etc.
- Aid in preparation for regulatory submissions including customer guidance on requirements and expectations from the Agencies, evaluation of existing data for submission readiness, risk assessment and fix of issues, and creation of submission documentation
- Consult customers on best practices by reviewing existing processes and providing recommendations for improvement
- Conduct User training and knowledge transfer
- Provide customer support to customers on CDISC implementation including analysis of reported issue and its resolution

Participate in development of P21 products

- Proposing and leading the implementation of new tools and functionality enhancements of existing systems
- Developing, managing, and implementing validation rules for data standards
- Testing the Pinnacle 21 tools by their active use

Promote P21 thought leadership

- Preparing papers and presenting them at industry conferences
- Conducting webinars

- Writing blog posts
- Assisting with preparation of white papers and training materials
- Supporting Pinnacle 21 users on forums and social media
- Participating in the industry initiatives like CDISC, PhUSE, HL7, etc.

What we're looking for

If you meet these criteria…

Must

- Minimum 5 years' experience in biostatistics and/or regulatory submission
- Minimum 5 years of training experience (i.e. new products, systems, or processes)
- Experience within CDISC, SDTM mapping and/or creation of ADaM datasets, and define.xml files
- Strong interpersonal, communication, writing, presentation and facilitation skills
- Detail-oriented with exceptional follow-through and superior organizational skills
- Ability to communicate with technical teams (e.g. developers and engineers) effectively to drive effective issue resolution
- Proven ability to work both independently and as part of a team; experience working as part of a distributed team
- Ability to gain security clearance for governmental contracts
- Must combine the ability of working smart and leveraging your team to get things done
- Willingness and ability to travel (about 10%)
- Come in smiling ☺

Plus

- Membership and participation within clinical trials industry user groups
- Experience within successful implementations of CDISC Standards and preparation of study data for regulatory submissions
- Willingness and ability for continuous professional development

… then we'd love to hear from you

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A bit about us

Pinnacle 21 is a startup making a big impact on regulatory review processes. Our flagship software, Pinnacle 21 Enterprise provides the biopharmaceutical industry with the key to a fast, efficient drug review process. It's the technology that drives FDA's 21st Century Review Initiative, ensuring that submission data is compliant, useful and ready for review — which enables a more efficient review process.

At the core of our company is our open-source project called Pinnacle 21 Community. We support users from the FDA, PMDA (Japanese Pharmaceutical Regulatory Agency), and almost every pharmaceutical company preparing a clinical submission. Building on top of this wide network, we continue to expand into new opportunities and grow our business.