IZIEL HEALTHCARE

# is proud to be amongst the TOP 20 MEDTECH SOLUTIONS PROVIDERS IN APAC 2018 !

## FEATURED COMPANIES

1 **Advent Access ,** Singapore

2 **Anatomics,** Australia

3 **Biocartis,** Australia

4 **Cardian Dimensions,** Australia

5 **Corin Group,** New South Wales

6 **Elastagen,** Australia

7 **Forefront Medical Technology,** Singapore

8 **Getinge,** Japan

9 **Getz Healthcare,** Singapore

10 **Imagine Biosystems,** Melbourne

11 **Immunodiagnostic System,** UK

**12 IZiel Healthcare** Pune, India

13 **LifeHealthcare,** Australia

14 **LockDown Medical,** UK

15 **Medtech,** India

16 **MetaOptima Technology,** Australia

17 **PolyNovo,** Australia

18 **SIS Medical,** Switzerland

19 **Varian,** India

20 **Vocera Communications,** Australia

MEDTECH OUTLOOK TOP 20 MEDTECH SOLUTION PROVIDERS IN APAC - 2018

## IZiel Healthcare

### Creating a Clearer Roadmap for US FDA Approval

Are you looking for a US FDA Approval or resolve findings from observations (I483) and/or warning letters?

IZiel Healthcare is your go-to partner that completes all the engineering documentation, software validation, and regulatory requirements for medical device companies to receive regulatory approvals and/or remediate the observations at the earliest.

IZiel works in collaboration with your team to develop the complete Design History File (DHF) including requirements management, risk management, process validations, and software validations using robust design controls process and quality system procedures. Thereafter, IZiel team works with their regulatory team in USA to complete the submissions (510k or PMA) and resolve queries, if any, from US FDA.


"IZiel's approach for an outcome-based delivery along with the cost-effective model by combining teams from India & US has worked very well for customers in USA, Europe, and Asia. Typically, competitors provide either engineering or regulatory services. We take complete responsibility, combining both the services to successfully deliver projects within budget and timelines" explains Sarvesh Mutha, MD, IZiel.

It all begins with a comprehensive Gap Assessment wherein the IZiel team lists down the shortcomings with the severity and prevalence. This detailed Gap Assessment enables both the companies to develop a roadmap and strategy to work towards completing the project.

Ankur Naik, MD, IZiel explains "For each of its projects, IZiel follows a detail-oriented approach to understand the gaps and develop solutions to close those gaps. We have to learn and understand the clients' products and identify all the regulatory compliance requirements for the class of products we are working on.


We then work with the engineering and quality teams and ensure that all the necessary documentation for design and process validations along with compliant quality system procedures are created. We adopt the V-Model methodology along with a Design for Six Sigma approach to document and validate the product. We utilize a very robust requirements management tool like Cognition Cockpit to develop the documentation in a speedy manner. In the process, we also train the engineering and the quality teams at the client's location and ensure a lasting change is made in the organization to continue producing quality products consistently."

Following this approach, the company is currently managing projects for various Class 1, 2 devices alongwith some work for Class 3 devices. IZiel is the sole reseller in the APAC region for Cognition Cockpit—a Medical Device Tailored Requirements Management System.

Additionally, IZiel has been providing design engineering and process improvement services. IZiel helps medical device manufacturers to increase their productivity, reduce rejection rate and develop automated solutions by employing Design for Six Sigma (DFSS) Methodologies, Design of Experiment, Statistical Process Control, Process Characterization and Optimization.

Mutha believes that projects for US FDA approval cannot be undertaken single-handedly and requires a team with an understanding of various requirements. "Our biggest asset is our people. We take pride in our strong team, comprising talented engineers who have previously worked in large organizations globally in the medical device space," he adds.

In the last three years, IZiel has witnessed a remarkable growth and look forward to collaborating with organizations abroad. The collaborations could be complementary service offerings and/or joint ventures for distribution and manufacturing of niche products. IZiel has developed the necessary industrial infrastructure, team, and technical capabilities to associate with international organizations for manufacturing and assembling their products in India.

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