US FDA 510(K)

CONSULTANTS

I3CGLOBAL

Table Of Content

About Us

Providing the Best Regulatory Solution with Quality & Data Security

We are a group of specialists with nearly 20 years of hands-on experience, dedicated to assisting our clients in meeting US FDA regulatory requirements. Our exceptional 510(k) team is adept at eliminating obstacles in Class I, II, and III medical device 510(k) (Premarket Notification) submissions.

We Provide

One stop solutions for US FDA Establishment Registration, Device Listing, FDA Pre & Post Audit support, 21 CFR 820 / GMP Implementation and FDA 510K

Technical

Quality documentation along with technical guidance for traditional and abbreviated 510ks.

US Agent

Support during 510k Interactive review and first point of contact

Registration

Establishment registration and listing after 510k clearance

Why Choose Us?

As a prominent 510k consulting organisation on a global scale, we have gained the trust of more than 350 plus manufacturers and specification developers. Our team consists of highly skilled subject-matter experts, assuring timely 510k clearance irrespective of the manufacturer's size or the regulatory knowledge of their internal team.

Our dedication goes beyond mere verbal or email communication; we painstakingly assemble the complete FDA 510k file on behalf of our clients and take full responsibility until the 510k clearance is obtained.

Project Team

01

Technical & Project Head

Responsible for overall quality of the 510k file and on-time submission.
Over 22 + years of regulatory experience medical device and pharmaceuticals. Lead auditor for GMP and ISO 13485.

02

Team Lead & Internal Reviewer(s)

Responsible for day-to-day monitoring of the project progress and quality.
Graduates or above in Biomedical / Pharma discipline. More than 3 to 6 years of experience in medical device regulation

03

510k DocumentationExpert(s)

Responsible for 510k preparation and customer interaction.
Graduates or above in Biomedical / Pharma / Engineering / Biology with 2-3 years of medical device documentation experience.

04

FDA US Agent

Responsible for 510k submission and creating payment gateway.
With over 12 years of experience, worked with multinationals and acted as the US Agent for foreign 510k applicants.

Stages of 510k

01

Identification of Device class, code and Predicative device

Crucial activity. Incase of NO Code and NO predicative device STOP proceeding further

02

Prepare 510k File

Consultants will prepare the file based on the information provided by the manufacturer. Non-clinical testing is mandatory along with other validation and shelf-life study report

03

Pay fee and submit file to FDA

FDA review fee $21760 or small business fee $5440 to be paid upfront before submission of the 510k file to FDA

Stages of 510k

04

Substantial Equivalence review comments

Respond all queries with appropriate evidence and justifications and resubmit the 510k file for additional information review

05

Interactive review comments

FDA may request for interactive review to collect missing minor information, post clearance of substantial equivalence determination

06

Receive clearance letter

Clearance letter with intended use send to the manufacturer

Timeline

510(k) Prepration and Testing

- 4-5 months with cooperation from the client team

FDA Review & Clearance

- 5-8 months depending on normal submission or bundled submission

CONTACT INFORMATION

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THANK YOU