MEDICAL DEVICE REGULATIONS

FAQs Session with CDSCO

Non Notified Devices Voluntary Registration Process

– Where Do We Stand & the Way Forward !

webinar

Organised by

AIMED

Supported by

Consultants Consortium of Chennai
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REGISTER

September 19, 2021
Sunday
4:00 - 5:00 PM

LET OUR REGULATOR SPEAK TO YOU

DO JOIN US TO GET ANSWERS TO YOUR FAQS ON VOLUNTARY REGISTRATION PROCESS

Voluntary Registration Process rolled out by CDSCO for Non Notified Devices is coming to an end by Sep 30th 2021. Industry Forums are receiving so many FAQs from various stakeholders over the last 2 months asking many questions on Voluntary Regn Process and raising wide range of questions on **WHAT HAPPENS FROM OCTOBER 1ST 2021.**

Hence AIMED (Association of Indian Medical Device Industry) is organising a session to enable the industry, stakeholders to get their FAQs addressed from the Regulator.

Some of the FAQs raised by stakeholders are captured below and we invite industry, stakeholders to register and join the session to discuss pertinent issues , challenges faced, if any.

This program is the initiative of AIMED , a leading Industry Platform for Make in India Manufacturers representing the Voice of the Industry.

AIMED

FAQs From Industry, Stakeholders

01

Is Voluntary Registration meant for Importers or Manufacturers ?

02

Is there any FAQs document released by CDSCO for Voluntary Registration Process ?

03

Is the Voluntary Registration meant for registering business entity OR for Products Registration ?

04

Is there any Video uploaded in CDSCO portal to guide businesses for Voluntary Registration ?

05

Is ISO 13485 / ICMED 13485 Certificate needed for Voluntary Registration ?

06

What will be the requirement for marking registration under product packaging? Would there be a timeline period permitted ?

07

Where is the inclusion of Startups in Registration as startups are not manufacturers, importers etc ?

08

Is there a fast tracking of registration process for startups funded by DBT, DST & Startup India recognised startups ?

09

Can we have dedicated cell for Startups at CDSCO Secretariat which can be enabled by Startup India for ease of handling ?

10

Can Startup India regd Med Tech Startups be given auto regn by CDSCO when startups provide addl information, if any needed ?

11

Can Startups meet ISO 13485, ICMED 13485 Certification criteria ? What do we do, if we don't qualify ?

12

Registration calls for ISO 13485 Certification ? Can we get the Certificate in one week's / one month's time ?

13

Which agencies are approved by CDSCO to issue IS0 13485, ICMED 13485 Certifications ?

14

Distributors, Retailers, Traders are covered under MSME Registration now. Will that information submitted to MSME be sufficient for doing voluntary registration ?

15

Will the timeline get extended for non notified devices ?

16

What happens if non notified devices don't get registered before Oct 1st 2021

17

Is there a hotline number OR voluntary regn enquiry desk created at CDSCO ?

18

Where do we get the final list of Notified devices ?

19

Can we have more Regulatory Support Cells for Industry during transition time as we need support?

20

Can Regulators address industry queries with more frequent sessions ?

PROGRAM AGENDA

Opening Remarks 4 00 - 4 10 PM	Mr Rajiv Nath Forum Coordinator AIMED

Voluntary Regn - Status Quo from CDSCO 4 10 - 4 30 PM	Dr V G Somani Drugs Controller General of India, CDSCO

Q & A - Audience Session 4 30 - 500 PM	Speakers
Dr V G Somani Drugs Controller General of India, CDSCO	Dr Ravi Kant Sharma, Deputy Drugs Controller (India), Medical Device Division, CDSCO

Vote of Thanks

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REGISTRATION DETAILS

Program is Open for all Industry Members, Stakeholders like Manufacturers, Traders, Distributors, Startups, Med Tech Businesses etc.

There is NO REGISTRATION FEE but Prior Registration is a MUST.

Registered Participants shall get Email Confirmation 2 days before the session.

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