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#### Sidharth Malhotra

Regulatory Affairs Group,  
Department of Pharmaceutics,  
JSS College of Pharmacy, JSS  
Academy of Higher Education  
and Research, Sri  
Shivarathreshwara Nagar,  
Mysore, Karnataka, India

#### Raghotham S

Regulatory Affairs Group,  
Department of Pharmaceutics,  
JSS College of Pharmacy, JSS  
Academy of Higher Education  
and Research, Mysore,  
Karnataka, India

#### Urooj Ahmed Khan

Ph.D. Research Scholar,  
Department of Pharmaceutics,  
School of Pharmaceutical  
Education and Research, Jamia  
Hamdard, New Delhi, India

#### Gaurav Kumar Jain

Assistant Professor, Department  
of Pharmaceutics, School of  
Pharmaceutical Education and  
Research, Jamia Hamdard, New  
Delhi, India

#### Balamuralidhara V

Regulatory Affairs Group,  
Department of Pharmaceutics,  
JSS College of Pharmacy,  
JSS Academy of Higher  
Education and Research, Sri  
Shivarathreshwara Nagar,  
Mysore, Karnataka, India

#### Correspondence

##### Balamuralidhara V

Regulatory Affairs Group,  
Department of Pharmaceutics,  
JSS College of Pharmacy,  
JSS Academy of Higher  
Education and Research, Sri  
Shivarathreshwara Nagar,  
Mysore, Karnataka, India

## ‘Sugam’ pathway for medical devices: An easy approach

**Sidharth Malhotra, Raghotham S, Urooj Ahmed Khan, Gaurav Kumar Jain and Balamuralidhara V**

#### Abstract

Medical Devices Industry is having tremendous growth in India. Central Drug Standard Control Organization (CDSCO) is the National Regulatory Authority under the Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India and is responsible for laying down the standards and ensuring safety, efficacy & quality for Medical Devices, Approval for Clinical Investigation. SUGAM is the online portal for submission of the various applications related to manufacturing and import of medical devices and their clinical investigation to CDSCO in India. The objective of the SUGAM is to enable paperless grant of various clearances by CDSCO, consolidate the Indian Drug Regulatory Framework by streamlining the CDSCO processes, permit higher level of transparency in drug regulatory processes. SUGAM is launched by the Ministry of Health & Family Welfare. The intentions of current study are to apprehend the software & online portal requirements and registration process of Pharmaceutical Products in India. The various applications that are submitted through this portal are permission to import drugs, medical devices, cosmetics and biological Permission to conduct clinical trials and BA-BE studies etc. SUGAM plays a major role in Pharmaceutical regulatory sector by making submission more simple and easy. This portal has taken India, a step ahead in the approval of pharmaceutical products.

**Keywords:** CDSCO, online portal, drugs, medical devices, biologicals

#### Introduction

The medical devices and surgical instruments are currently not covered under the regulatory framework in India. However, any device which is intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified by the Central Government by notification in the Official Gazette would be considered as a drug under the D&C Act and provisions of D&C Act and Rules made therein would be applicable on such device. From time to time, Ministry of Health and Family Welfare, Government of India vide gazette notifications has notified certain medical devices as drugs under the D&C Act.

Prior to 2005, only medical devices such as disposable hypodermic syringes, tubal rings, condoms, metered dose inhalers, were required to be registered in India. In 2005, the Ministry of Health and Family Welfare (MOHFW) vide gazette notification dated 6 October 2005 further notified 10 sterile devices (“Notified Medical Devices”) to be considered as drugs and consequently regulated their import, sale and manufacture of the D&C act.

A medical device is defined according to Schedule M-III creates a specific definition of medical devices as separate from drugs. Unlike a drug, a medical device is defined as a medical tool “which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means.” Medicinal products covered by the Drugs and Cosmetics Act (DCA) will not fall under Schedule M-III. If there is any uncertainty about whether the product falls under the drug or medical device category of the DCA under this schedule, regulators will consider the principal mode of action of the product.

Medical device regulation, prior to sale, is relatively new in India, although pharmaceuticals have been regulated by the Central Drug Standard Control Organization (CDSCO) since 1940, under the Ministry of Health and Family Welfare. The Indian government proposed regulatory guidelines for pre-market approval of medical devices in 2008, through amendments to the 1940 Drug and Cosmetics Act (DCA). New guidelines on applying drug rules to medical devices were introduced in 2012, and an updated bill will be presented to the Indian Parliament in 2013.

The new bill is expected to bring all medical devices sold in India under the purview of the government agency charged with regulating medical devices: the Central Licensing Approval Authority (CLAA) under the CDSCO.

The central licensing approval authority (CLAA), a branch of the CDSCO, will serve as the main regulatory body for medical devices. The CLAA will classify medical devices, and any manufacturer seeking a less stringent classification must send justification to the CLAA. In consultation with an expert panel on medical devices, the CLAA also will set and enforce safety standards, appoint notified bodies to oversee conformity assessment, conduct post-market surveillance, and issue warnings and recalls for adverse events. All medical devices will undergo conformity assessment procedures to ensure compliance with quality and safety standards before they are allowed on the Indian market. The CLAA will adopt as regulatory standards the Bureau of Indian Standards (BIS) and International Organization for Standardization (ISO) specifications for quality management systems. To meet these standards, medical devices must be designed and manufactured in a way that achieves their intended purpose and does not compromise patient health or safety.

Classification of medical devices under Schedule M-III, medical devices will be divided into four classes according to their risk level: A, B, C, and D. Class A will include low-risk devices such as thermometers and tongue depressors. Low- to moderate-risk devices such as hypodermic needles will fall under Class B. Class C will cover moderate-to high-risk devices such as lung ventilators and bone fixation plates; and high-risk devices heart valves and implantable defibrillators, for example will comprise Class D. The regulatory procedures for medical devices will vary according to their class. In general, higher-risk devices will require more regulations and a more stringent conformity assessment process. The regulatory procedure for medical devices varies according to their class. The objective of the present study is to provide an overview of Regulatory guidelines for medical devices are importing, registering, and licensing and clinical trials in India. These new Central Drug Standard Control Organization (CDSCO) documents may be used as a basis for any future comprehensive changes in medical device regulations in the country.

For Class A devices, manufacturers may perform their own conformity assessment procedures. However, for Class B, C and D devices, the CLAA, in consultation with the BIS, will publish a list of notified bodies authorized to perform conformity assessment. Medical device manufacturers must submit an application for assessment to one of these notified bodies. The necessary application materials will include technical documentation, corrective and preventative action procedures, as well as information about the organization and goals of the business. In the case of Class C and D devices, further information and clinical investigation may be required. After receiving all of the application materials, the notified body will examine and assess whether the device conforms to BIS and ISO standards. Notified bodies also will conduct unannounced audits of manufacturing facilities to ensure that actual manufacturing practices match those described in the documentation. Medical devices that conform to proper standards must bear the Indian Conformity Assessment Certificate mark, which will allow them to be placed on the market and to move freely throughout India.

In current scenario, there is an immense need to use medical devices effectively to address the huge gap between demand

and supply of healthcare services in India. The medical devices sector in India is at a nascent stage with most of the indigenous manufacturing restricted to medical consumables. Medical device industry is rapidly moving into an era of growth driven by unmet clinical needs and greater focus on domestic manufacturing. Indian medical devices market is the 4<sup>th</sup> largest in Asia and in the list of top 20 in the world. The medical device sector represents 9% of the overall Indian healthcare industry. It was estimated at the value of USD 4billion in 2014 and is growing at a compounded annual growth rate (CAGR) of 16% over the period of five years. In true sense, imports still constitute over 75% of the current medical devices market. The rapidly expanding sector presents immense opportunities to local manufacturers and start-ups as well global players. There is a big shift in health burden from communicable to non-communicable diseases, which in turn is driving key medical devices segment. There is a huge demand for both cutting-edge precision technologies as well as affordable low technology.

### Sugam

It is a portal used for application and grant of licence or permission for the following:

- 1) Blood Bank License.
- 2) NOC to manufacture unapproved drugs for the purpose of export.
- 3) Conduct BA/BE studies.
- 4) NOC to obtain test license for unapproved or new drugs.
- 5) Registration for import of cosmetics.
- 6) Indigenous manufacture and Import of Medical device and Diagnostics.
- 7) Registration for global clinical trial.
- 8) Pay Online any fee as required for all above applications in a Secure and convenient manner and Save time.
- 9) Import of drugs for the purpose of test or analysis.
- 10) Import of drugs for personnel use,
- 11) Registration for import of drugs.
- 12) Indigenous manufacture and Import of Biologicals including rDNA.
- 13) Registration of Ethics committee.

### Benefits of the system

- SUGAM portal provides the single window for all its stakeholders to access the services provided by the portal by implementing role based access control and actions.
- It has consolidated the entire Drug Regulatory framework at centre and provides a centralized dashboard for the monitoring the various regulatory clearances all over the country.
- SUGAM portal provides high level of transparency to its stakeholders as status of the submitted applications can be tracked from applicant dashboard.
- SUGAM enables ease of business by providing the integrated workflow right from making an application for grant of permission/ license, online payment, online review process, query management and grant of permission/license online.
- SUGAM provides a framework for viewing and replying to the deficiencies raised during processing.

### Registration steps for application for import and indigenous manufacturing of medical devices

1. Open link "cdsconline.gov.in" and then click on "Online System for Medical Devices" to register, on the window as shown in Figure 1.1.

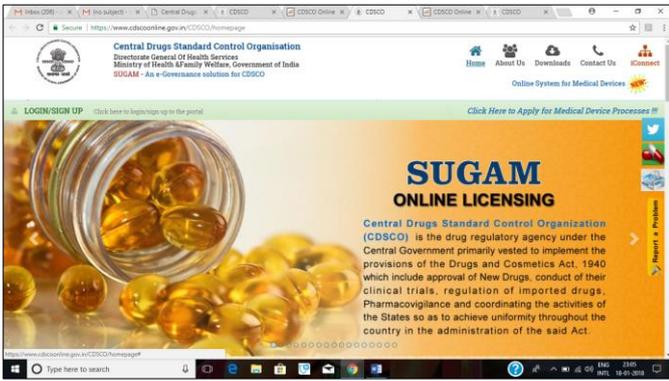


Fig 1.1: Overview of CDSCO website

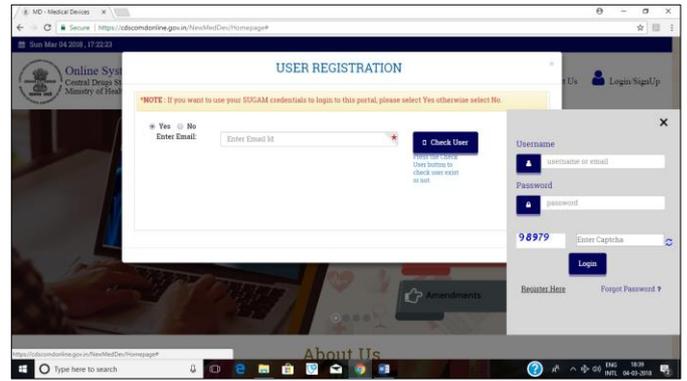


Fig 1.4: User registration window

**Note**

- Applicant who can register on the portal are Corporate, Indian Agent, Importer, Foreign Enterprise holding Indian Subsidiary.
- Manufacturing Unit can also directly register on the portal.
- Corporate will create login credentials for the manufacturing unit and these credentials will be used by the manufacturing unit for login on the portal.

2. A new window will open as shown in Figure 1.2



Fig 1.2: Window depicting online system for medical devices

3. Click on “Login/Sign Up” link to register on the portal, a new pop up will open, as shown in Figure 1.3 to register or login.

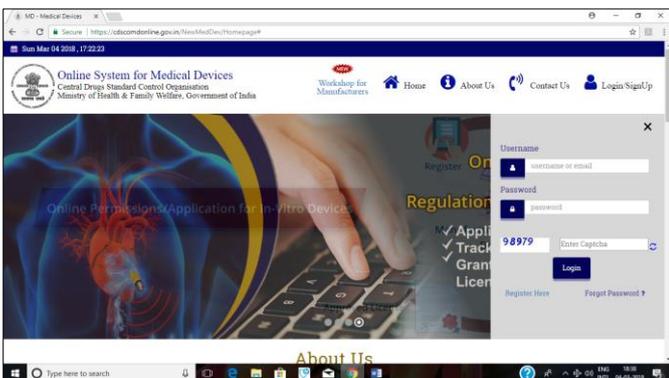


Fig 1.3: Registration window under online system for medical devices

4. Select “Register Here” icon to register as new user, a new pop up will open, as shown in Figure 1.4 to select the user registration.

5. Enter the email id and select “Yes”. Click on “Check User” link and new window appears as shown in Figure 1.5

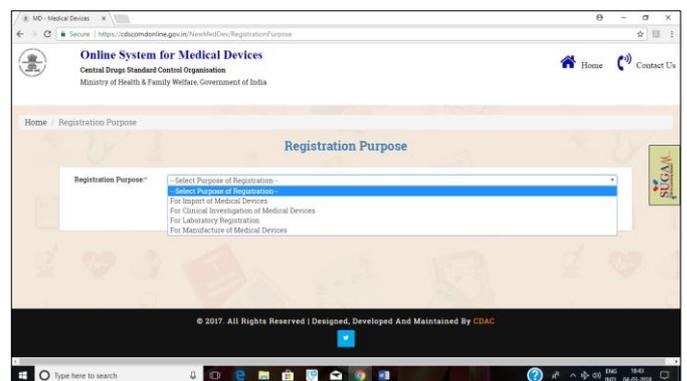


Fig 1.5: Window depicting registration purpose

6. Upon selection of the type of application the form as shown in Figure 1.5 select the Submit button and the form i.e. Registration Form as shown in Figure 1.6 will appear.

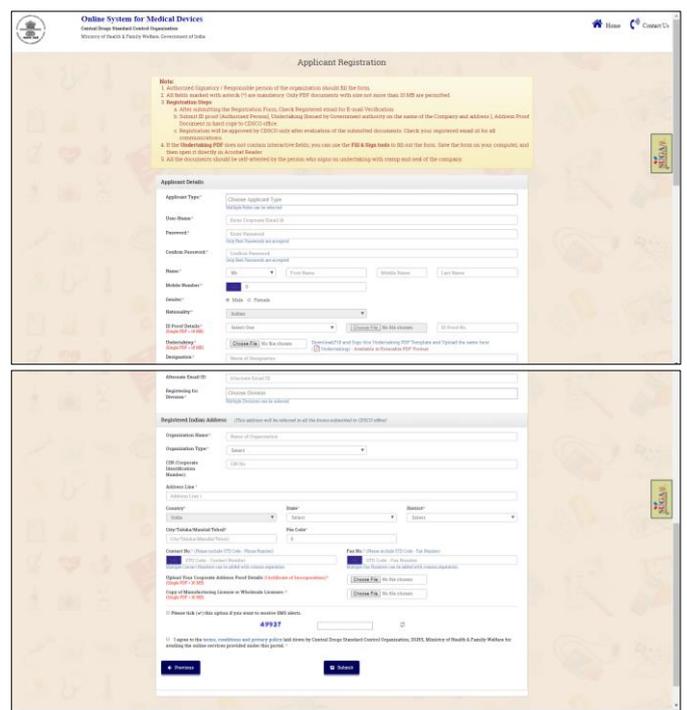


Fig 1.6: Registration form for SUGAM

**Note 1**

- Username will be corporate email id and it should be unique, which can be used as user name for future use.
- Password length should be at least 6 characters long with at least one number, one lowercase and one uppercase letter and one special character.
- User must upload necessary documents like ID Proof Details, Power of Attorney and Corporate Address Proof Details and user should keep these documents ready in PDF format before sign up process.
- If you select the checkbox for “Do you want to receive SMS alerts?” at the time of registration, you will receive the registration and verification message on your registered mobile number.
- User can register by filling the form as shown in Figure 1.6.

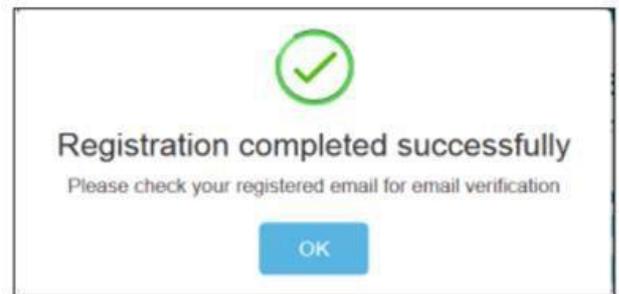
**Note 2**

- After clicking on submit button, a confirmation link will be sent to user’s registered email id to verify registration.
- User can activate account by clicking on the link sent to the registered email id.
- When user will click on the verification link sent to user's registered email id, application will be sent for approval to the concerned authority (CDSCO Officials).

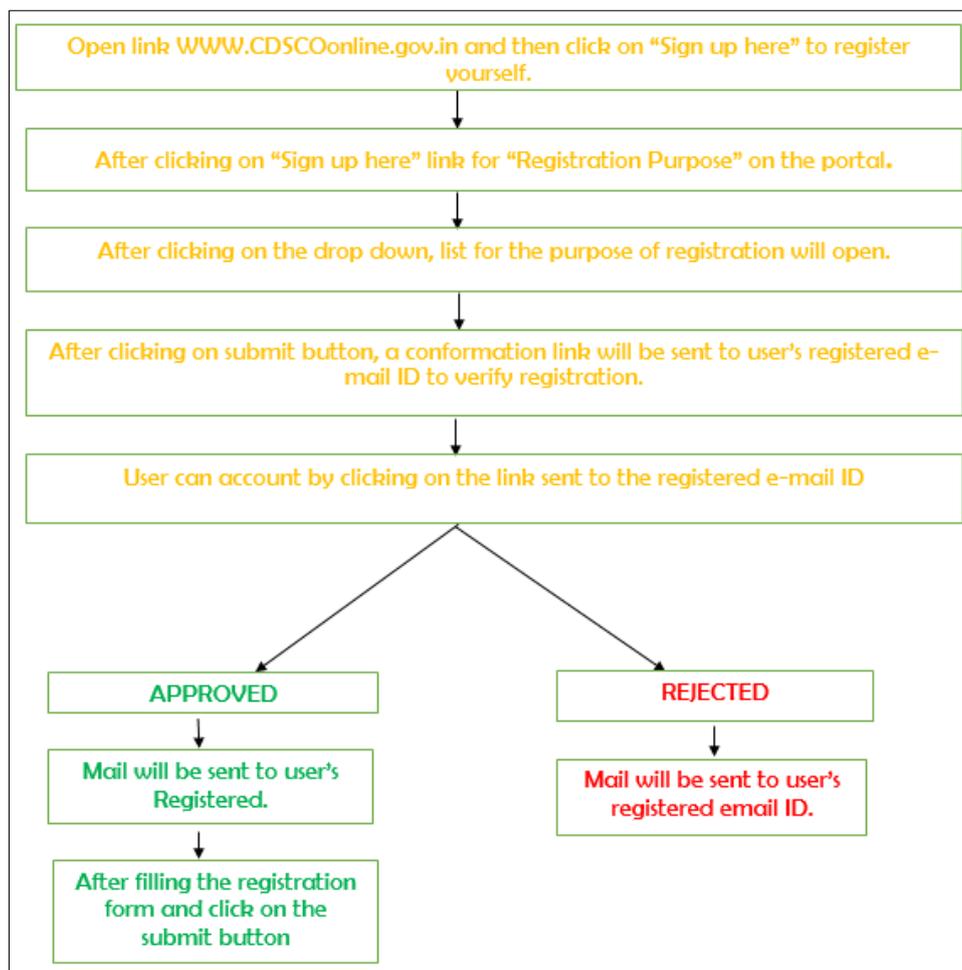
- In case of approved application, a mail will be sent to user's registered email id.
  - In case of rejected application, a rejection mail will be sent to user’s registered email id.
7. Enter Login Credentials in the sign in box and click on "Login", as shown in Figure 1.3.

**Note**

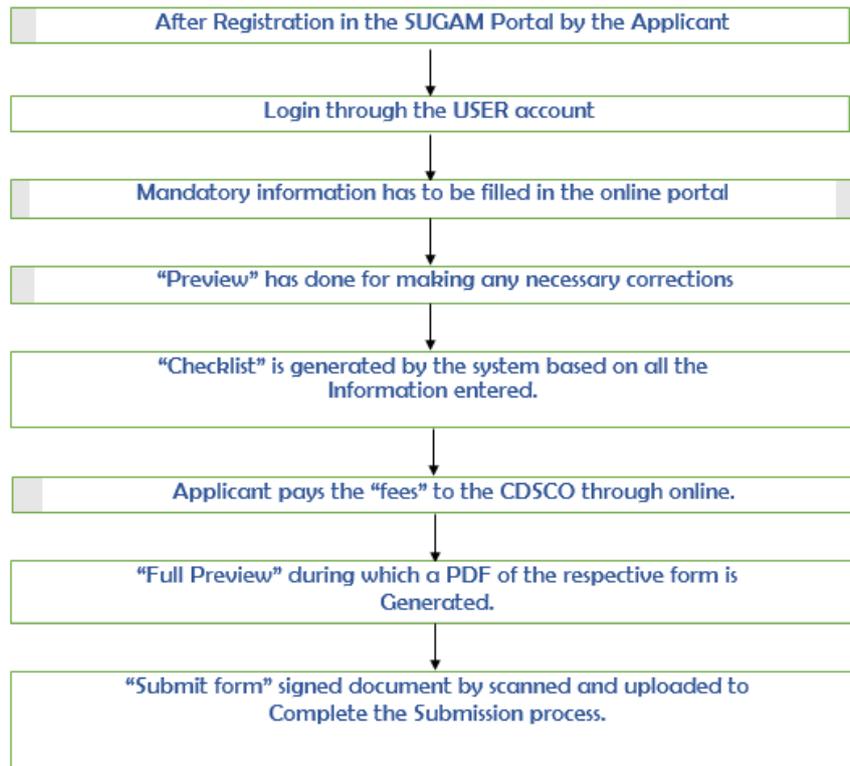
- It is advised for the user to check their valid registered email id and valid registered phone number from time to time, because all the communication before successful registration process will be done through user's valid registered email id and phone number (via SMS ).



**Registration process in SUGAM portal**



## Discussion



## Conclusion

Overall review of the online service for filling applications for manufacture or import registration of Medical Devices have been carried out and it has been observed that in recent months there is a continuous rise in the percentage of online applications vis-s-vis offline mode. The increasing trends towards filing online applications by the applicants are very encouraging through SUGAM portal. This trend commensurate with the Government's vision of Digital India.

Understanding the regulatory reforms imminent in India will be crucial for foreign companies looking to enter or expand their business in India's medical markets. It is hoped that the guidelines are implemented and regulated properly with effective outcome. This article highlights current regulations pertaining to applications for medical device registration certificates, medical device clinical trials, and medical device manufacturing/importation licenses.

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