

**CONSULTANTS CONSORTIUM OF CHENNAI (CCC),
ASSOCIATION OF INDIAN MEDICAL DEVICES INDUSTRY (AIMED) &
PREVENTIVE WEAR MANUFACTURERS' ASSOCIATION OF INDIA (PWMAI)
JOINTLY ORGANISING INDUSTRY EDUCATION PROGRAMS ON**

MEDICAL DEVICES QMS BASED ON ISO 13485 AND ICMED 13485 CERTIFICATION SCHEMES

Online Training

Batch - 4

1ST JUNE 2020 ONWARDS ...

TIME : 4.00 PM TO 6.00 PM

About Consultants Consortium of Chennai (CCC)

Consultants Consortium of Chennai (CCC) is an Association of Management Systems Consultants, registered under the Tamilnadu Societies Registration Act, 1975.

The Key Objective of CCC is to work in alignment with the National Quality Mission launched by the Government of India by educating the industry about the role and importance of Standards, Certifications and Regulations in the country as well as in the global markets.

CCC strives to encourage Responsible Consulting through Members of its Association and focus is to Standardize Consulting Practices in alignment with changing market and industry needs in a dynamic manner.

The focus is also to identify areas and industries in which the consultants in the profession of Management Systems Consulting can contribute to the betterment of the society and the country and to promote Management Systems Consulting in such areas or industries.

One of the core objectives is to collaborate with various Industry platforms, Trade Associations, Chambers of Commerce, Management Associations, Apex Bodies of Government or Quasi Government Organization to contribute to the betterment of the industry initiatives, which will in turn contribute to the betterment of the society.

Objective of this Training

CCC has received a request from AIMeD to conduct online training programs for its Members who are into PPEs manufacturing about ISO 13485 & ICMED 13485 Certifications.



Our Approach

CCC shall be conducting the training programs as online series and the rollout plan is as mentioned below :-

- QMS Standards based on ISO 13485 and ICMED 13485 Certifications shall be addressed
- Entire program structure is divided into 7 modules
- Few Trainers shall handle various modules
- Each module can further be split into 2 sessions so that trainers can handle the sessions in detail
- Each session will be conducted for 2 hrs - 1 hr 30 minutes for Training, 30 minutes for Q & A
- Time Slot : 4:00 – 6:00 PM
- Each Session can have 30 participants to make it more interactive
- Total number of sessions for each batch would be 13 sessions in total
- Platform to be used – ZOOM – protected meetings though enabling meeting room, access restricted to invitees only.
- Each Participant will have to take an online assessment after completion of each module. Certificate of Participation shall be issued to Participants after evaluation of their test assessment scores.

Training Modules

- **Module 1 - 2 Days** - Regulations for PPEs in India, US & EU, EUA and Normal route, Birds eye view of Standards , Conformity Assessments, Test Methodologies to be followed in India and Global Markets, Introduction to ISO 13485 & ICMED 13485 Standards requirements
- **Module 2 - 3 Days** - ISO 13485 & ICMED 13485 - Product Standards, Regulatory Requirements for PPEs, Planning of Product Realization and Design and Development of PPEs, CE Marking Introduction
- **Module 3 - 2 Days - ISO 13485 & ICMED 13485** - Risk Management – Risk based thinking approach, Corrective Action based on ISO 13485
- **Module 4 – 2 Days - ISO 13485 & ICMED 13485** - Bio compatibility & Sterility, Microbiology issues - ISO 10993:2009 Requirements, Sterilization practices
- **Module 5 - 1 Day** - Coveralls Manufacturing - Technical requirements, Test Standards and practices
- **Module 6 – 1 Day - User Industry Inputs-** What do ICU Teams, Critical Care Experts, Healthcare teams look for in PPEs – usability features, comfort, safety, quality etc. Clean Room Standards & Guidelines. ISO 13485 & ICMED 13485 - Labelling Requirements
- **Module 7 - 2 Days - CE Certifications, USFDA Approvals, ISO 13485 & ICMED 13485** - Approach to ICMED Certification

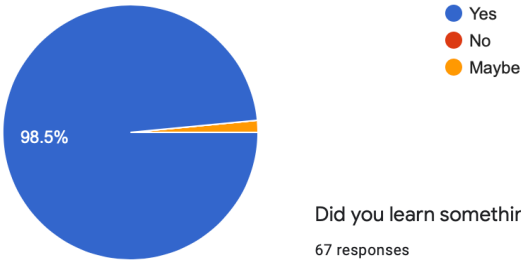


What we did so far..



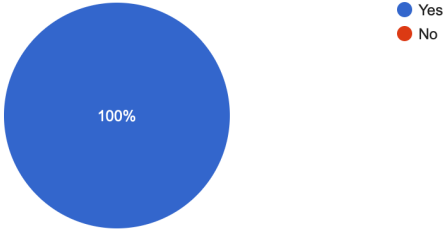
Do you think really the training is useful?

66 responses



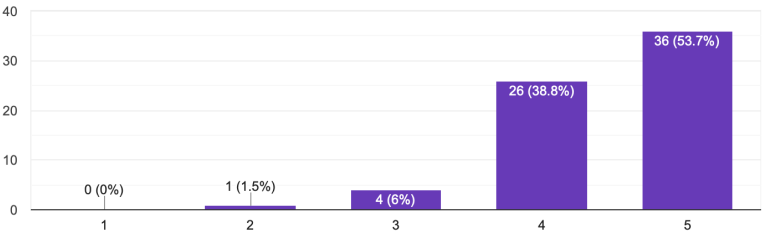
Did you learn something new from this training?

67 responses



Rate the usefulness of the training ?

67 responses



Previous Batches Feedback..

- The sessions are really very interesting and informative. I missed the 1st one. Please send the details. Regards **Pravin Gulati, Director, SHI Mediwear P Ltd**
- Mam I want to proceed for certification and registration with CDSCO. Is there any well known authentic consultant can you recommend for my company as we have taken the certifications twice but with your training courses I came to know that they were not very much knowledgeable. Whatever they recommended I executed it but now I am aware about the missing information. We are based in Kolkata, West Bengal state.- **Mrs Asha Shaw, Director, Premium healthcare disposables Pvt Ltd**
- Mr.Karthi's classes were excellent.- **Geetha Kowlagi, Jaeger Products Pvt.Ltd, Chennai**
- Thank you for the session. Very detailed and informative- **Nikunj Kedia, Bellcross Industries Pvt Ltd, Mumbai**
- It's nice and good experience in learning about ICMED and ISO - **D.Annamalail, BALAJI MEDITECH**
- It gives Clarity in the concepts - **Ravindra V.Kamat Kiran Medical Systems, A division of Trivitron Healthcare Pvt. Ltd.**
- Its really informative as well as really needed for future course of action. - **Ankur Vyas, Regal Healthcare**
- Trainer has indept knowledge of the field. And is very well versed. He explains easily if not understood. Only sometimes it get too theoretically - **Nikunj Kedia**
- some issues are in connectivity. rest all fine - **Harjinder Singh, Vital Healthcare**
- Very Helpful to understand basic concepts in QMS and new requirements in ICMED 9000 - **Donald S K, Kanam Latex Industries Pvt Ltd**
- We requesting to refer how this system help for mask and PPE Kits manufacturer - **Nalliah Kannan, Loyal Textile Mills**
- Can make it more interactive with industry examples and case studies - **Kanav Gupta, Business Coordination House (BCH)**
- Informative , well , but needs t be more presentable - **Dr Pramod Bajaj, Sperm Processor Pvt Ltd**
- Right training in the right time - **SUBRAMANIAN N, Pinnacle Technologies**



Program Fee

- Rs 5000 for each participant for all 7 modules spread across 13 sessions
- 20% discount for AIMED Members is extended. Fee for AIMED Members is Rs 4000.
- PWMAI Members Discount :
 - For 5 registrations from same Organisation – 20 % discount
 - For 3 registrations from same organisation – 15% discount
 - For less than 3 registrations from same organisation – 10% discount

Who Should Attend ?

All Medical Device Manufacturers, Testiles and Garmet Industries & Startups, especially recently manufacturing of PPE Kit components like coveralls, masks, goggles etc

Members participation for this batch is restricted to max of 30 participants only.

Registration Details

Step 1 :Make Payment through NEFT as follows :

Name of the Account Holder

Consultants Consortium of Chennai

Bank Name – Indian Overseas Bank

Branch Name – RK Nagar Branch

Bank Account No – 064102000001856

Type of Bank Account – Current Account

IFSC Code – IOBA0000641

Step 2 :Fill up the registration form with UTR number details for payment madeLink to Regn Form - <https://bit.ly/3aymhgJ>

Step 3 :Invitation for ZOOM meet shall be sent by mail to Regd participants

Step 4 :Online Test Links also will be shared by mail after the completion of each session

Contact Coordinator

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