BIOLOGICAL SAFETY & EFFICACY EVALUATION OF MEDICAL DEVICES

24 September 2018

	9:00 -10:00 AM **Welcome and briefing** Inaugural address –
	10:00- 10:15 AM **Energising gap**
	10: 15 – 10:45 AM **Session 1:**Medical device classification as per Regulatory norms
	10:45 – 11:30 AM **Exercise 1:** Medical device classification
	11:30 – 12:00 noon **Session 2:** Evaluation and testing within a risk management process – ISO 10993- 1
	12:00 – 12:45 PM **Exercise 2 :** Systematic approach to biological evaluation of medical devices, presentation and discussion
	12:45 – 1:45 PM **Lunch Break**
	1:45 - 2:15 PM **Session 3:** How material characterizations support the biological evaluation process?
	2: 15 – 3:00 PM **Exercise 3:** Quiz on physicochemical characterization
	3:00- 3:15 PM **Energising gap**
	3:15- 3:45 PM **Session 4:** Tests for in vitro cytotoxicity – ISO 10993-5
	3:45 – 4:30 PM **Exercise 4:** Exercise on cytotoxicity data interpretation

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	9:15 – 10:00 AM **Session 5:** Toxicology evaluation of medical devices – I- ISO 10993-3,6,10,11
	10:00 – 10:30 AM **Exercise 5:** Discussion on toxicity evaluation – Queries raised by the participants
	10:30- 10:45 AM **Energising gap**
	10:45 – 11:15 AM **Session 6:** Blood compatibility evaluation of medical devices - ISO 10993-4
	11:15 – 11:45 AM **Exercise 6:** Exercise : Case study on blood compatibility
	11:45 – 12 :15 AM **Session 7:** Biocompatibility and preclinical evaluation of medical devices – Histopathology aspects
	12:15 – 12:45 PM **Exercise 7 :** Histopathology - discussion on tissue response to medical devices
	12:45 – 1:45 PM **Lunch Break**
	2:30 – 5:30 PM **Lab Visit:** Biomedical Technology Wing – Division of Toxicology, Division of Experimental Pathology, Division of Thrombosis Research, Division of In Vivo Models & Testing, Division of Microbial Technology

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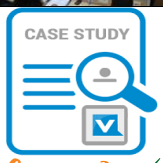
	9:15 -9:45 AM **Session 8:** Product release studies - Sterility test In Vitro gentoxicity and bioburden
	9:45 – 10:30 AM **Session 9:**Product release studies : residual analysis –
	10:30- 10:45 AM **Energising gap**
	10:45 – 11:15 AM **Session 10:** In vivo safety /performance evaluation of medical devices
	11:15 – 12:00 **Exercise 8:** Case study on in vivo safety /performance evaluation of medical devices
	12:00- 12:30 PM **Session 11:** Development of a medical device evaluation matrix
	12:30 – 1:15 PM **Exercise 9 :**: Developing a evaluation matrix on a specific device
	1:15 – 2:00 PM **Lunch Break**
	2:00- 2:30 PM **Session 12:** Device regulations
	2:30 – 3:00 PM **Session 13:** Regulatory submissions
	3:00 – 3:30 PM **Self Evaluation:** Biological evaluation – Medical devices
	3:30 - 3:45 PM **Energising gap**
	3:45 – 4:30 PM **Feedback and conclusion**