



**MDRC - Inter-American Coalition for Regulatory Convergence
in the Medical Technology Sector
External Stakeholders Meeting**

Date: 10 Oct 2023

Time: 9:00 – 17:40 CST (UTC-6)

Platform: Hybrid (In-person & Zoom) Please click [here](#) to register to attend either virtually or in person.

Venue: Auditorio del Cineteatro, Universidad de El Salvador, Ciudad Universitaria, Final, 25 Av. Norte, San Salvador.

Language: Simultaneous interpretation English, Portuguese and Spanish

| Time | Topic |
|---------------|--|
| 9:00 - 9:10 | Housekeeping Message and Welcome Remarks Sandra Ligia González, IACRC |
| 9:10 – 9:40 | Medical Device Regulatory Convergence, COVID 19 (MDRC). The Journey (30 min) Sandra Ligia González, MDRC <ul style="list-style-type: none"> • Latin America • Africa • Asia Q&A 10 min |
| 9:40 – 10:50 | Conversation on Emergency Use Authorization (EUA). Where we were and where we are after COVID-19 Pandemic? (90 min) Moderator: Roberta Mele Mazza, Executive Committee IACRC, CADIEM/CAPRODI TBC <ul style="list-style-type: none"> • Brazil <ul style="list-style-type: none"> ○ Marcella Abreu, ANVISA (Virtual) ○ Carlos Gouvêa, CBDL (Virtual) • Colombia <ul style="list-style-type: none"> ○ Industry Representative • Mexico <ul style="list-style-type: none"> ○ COFEPRIS, Heriberto Martínez Márquez ○ Verónica García, AMID Q&A 10 min |
| 10:50 – 11:10 | Coffee Break |
| 11:10 – 12:15 | Turning Reliance into a Reality. The Role of the Industry (65 min) Moderator: Sandra Ligia González, MDRC GMTA Position Paper on Reliance – How can it help? <ul style="list-style-type: none"> • Argentina – CAPRODI & CADIEM • Brazil – CBDL Josely Cevallos • Chile – ADIMECH Gabriela Garnham • Colombia – ANDI Marisol Sánchez • Ecuador – ASEDIM – Cristina Murgueitio • Mexico – AMID – Verónica García • Peru – COMSALUD & CMDMAA - Juan Olivares y Malena Tapia Q&A 15 min |
| 12:15 – 13:15 | Lunch |



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| <p>13:15 – 14:10</p> | <p>Electronic CFG/FSC – A proactive approach to a new reality. Part I (55 min) Moderator: Marina Carvalho, MDRC eCFG/eFSC benefits and risks for a regulator – Ethny Obas, US FDA CDRH (20 min) Position paper on eCFG/eFSC – Marina Carvalho, IACRC (20 min) Q&A 15 min</p> |
| <p>14:10 – 15:00</p> | <p>Electronic Regulatory Tools – A proactive approach to a new reality. Part II (50 min) Reliance - Leveraging regulators' data bases Moderator: TBC</p> <ul style="list-style-type: none"> • Carolina Magnatti, ANMAT (10 min) Virtual • Hélio Bonfim de Macedo Filho, ANVISA (10 min) • Vesa Vuniqui, US FDA (10 min) <p>Q&A 20 min</p> |
| <p>15:00 - 15:30</p> | <p>Turning Reliance into a Reality. The Brazilian proposal. (30 min) Moderator: Sandra Ligia González, MDRC (20 min) Augusto Geyer, ANVISA (Virtual) Q&A 10 min</p> |
| <p>15:30 – 15:50</p> | <p>Coffee Break</p> |
| <p>15:50 – 16:40</p> | <p>Open Public Consultations – Opening a pathway for Reliance (50 min) Moderator: Leticia Fonseca, IACRC</p> <p>Argentina – CADIEM & CAPRODI Ecuador - ASEDIM Mexico - AMID Peru – COMSALUD & CMDMAA</p> <p>Q&A 10 min</p> |
| <p>16:40 - 17:15</p> | <p>Turning Reliance into a Reality. The Experience of Singapore Moderator: Sandra Ligia González, MDRC Rama Sethuraman, Health Science Singapore 20 min (Virtual) Q&A 15 min</p> |
| <p>17:15 – 17:30</p> | <p>Closing Remarks <i>Sandra Ligia González, IACRC</i></p> |
| <p>17:30 – 19:30</p> | <p>Reception for in-person participants</p> |