



Annual Report Template v.3

Approved By: 2023 Board of Directors

Date Approved: 01 March 2023

# 2022 Annual Report

Assembled By: Michelle Sands, President, 2022

Annual Meeting

18 January 2023

~Zoom Presentation~

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## 1. PRESIDENT'S STATEMENT

The President offers a sincere debt of gratitude to our many volunteers, committee members, members, and interested third parties for making 2022 another successful year. While the pandemic had continued to thwart our efforts for in-person events, we made the best of it by continuing to hold our monthly meetings virtually. It has been a pleasure to work with the Board of Directors (BOD) throughout 2022 and I look forward to seeing the great things that the 2023 SDRAN BOD has in store for the organization.

## 2. LEADERSHIP

**Table 1: Board of Directors**

Board of Directors for 2022	
Title	Name
President	Michelle Sands
President-Elect	Olivia Yu
Past-President	Sasi Mudumba
Secretary	Jamie Brugnano
Treasurer	Daniel Yeh
VP of Education	Theresa Falls
VP of Member Relations	Illham Naili
VP of Mentoring	Jennifer Grodberg
VP of Programs	Carlos Torres / Gabriela McCoole
VP of Website & Communications	Position Not Filled

## 3. ACCOMPLISHMENTS

**Table 2: Accomplishments**

Position	Name	Accomplishments
President	Michelle Sands	<ul style="list-style-type: none"> <li>Supported the BOD to achieve their individual goals.</li> <li>Promoted and implemented new strategies to enhance SDRAN's programs and member services.</li> <li>Implemented the 2022 SDRAN Survey.</li> </ul>
President-Elect	Olivia Yu	<ul style="list-style-type: none"> <li>Recruited new board members specifically for President-Elect, VP Programs, and Secretary positions for 2023.</li> </ul>
Past-President	Sasi Mudumba	<ul style="list-style-type: none"> <li>Prepared 2021 Annual Report</li> <li>Assisted BOD with the tasks where needed.</li> </ul>



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		<ul style="list-style-type: none"> <li>Managed launch of newly designed website and streamlined the process for maintenance.</li> <li>Assisted Mentoring Committee in designing and creating Google Forms to simplify the process of collecting and managing the information.</li> <li>Managed G Suite training and transfer of emails for the 2023 Board Members.</li> </ul>
Secretary	Jamie Brugnano	<ul style="list-style-type: none"> <li>Ensured the SDRAN BOD adhered to the bylaws at each monthly meeting.</li> <li>Maintained the SDRAN BOD documentation in G-Suite, which includes but is not limited to BOD Monthly Meeting Agendas, BOD Monthly Meeting Minutes, BOD Action Items, BOD Lessons Learned, and information on in person meeting locations.</li> </ul>
Treasurer	Daniel Yeh	<ul style="list-style-type: none"> <li>Maintained a balanced annual budget.</li> <li>Maintained proper accounting records for financial audit.</li> <li>Transitioned all financial activities using the new registration/payment system.</li> </ul>
VP of Education	Theresa Falls	<ul style="list-style-type: none"> <li>Offered RAC Exam Preparatory Sessions accessible online by Zoom (international)</li> <li>Preparatory Sessions ran from April through July (Summer) and September through December (Fall)</li> <li>Devices: 14 sessions (including intro session); 21 registrants (Summer), 4 (Fall)</li> <li>Drugs: 15 sessions (including intro session); 23 registrants (Summer), 7 (Fall)</li> <li>Continued to offer RAC Scholarships to RAC recipients (1 awarded)</li> <li>Obtained RAPS discounts on textbooks and practice exams</li> </ul>
VP of Member Relations	Ilham Naili	<ul style="list-style-type: none"> <li>Organized, in conjunction with VP of Programs, the on-line Open House with breakout rooms for RA Devices, RA Drugs, and QA discussions &amp; breakout rooms with University Representatives</li> <li>Set up monthly email reminders to members with recently or soon-to expire memberships to renew</li> <li>Provided support to members during the transition to EZ Sign Up</li> <li>Maintained monthly program survey reports</li> <li>Created surveys for RAC sessions</li> <li>Secured a location for the Member Appreciation Event</li> </ul>

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VP of Mentoring	Jennifer Grodberg	<ul style="list-style-type: none"> <li>Gave program orientation prior to accepting applications to clarify program expectations</li> <li>Initiated electronic application process</li> <li>Held a Zoom group mini-mentoring session to program applicants who were not assigned a mentor this session</li> <li>Led Zoom interim program group sessions with mentors and mentees to exchange experiences/ideas plus identify areas of optimization</li> <li>Hosted end-of-mentoring-session group dinner</li> </ul>
VP of Programs	Carlos Torres/ Gabriela McCoole	<ul style="list-style-type: none"> <li>Offered 10 monthly program events online</li> <li>Provided certificates of attendance to participants</li> <li>Organized, in conjunction with VP of Member Relations, the on-line Open House with breakout rooms for RA Devices, RA Drugs, and QA discussions &amp; breakout rooms with University Representatives</li> </ul>
VP of Website and Communications	Position not filled	<ul style="list-style-type: none"> <li>Implemented new website improvements and roll out</li> <li>Implemented new registration system for SDRAN classes and events</li> <li>Increased social media outreach via LinkedIn to communicate various events</li> </ul>

#### 4. EDUCATION

Committee Members:

- Theresa Falls, VP of Education
  - Bharathi Hattiangady
  - Hua Deng
  - Huong Huynh
  - Jamie Brugnano
  - Jing Li
  - Michelle Sands
  - Nanditha Tula
  - Shivam Mishra

**Table 3: Details of the RAC Classes and Participants**

Class Name	No. of Participants	Location
Spring/Summer RAC Drugs Prep Sessions	23	Online/Zoom - Live
Spring/Summer RAC Devices Prep Sessions	21	Online/Zoom - Live
Fall RAC Drugs Prep Sessions	7	Online/Zoom - Pre-recorded
Fall RAC Devices Prep Sessions	4	Online/Zoom - Pre-recorded

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**Table 4: SDRAN RAC Preparatory Instructors**

RAC Introductory Session	RAC Drugs Sessions	RAC Device Sessions
Lequina Myles	Amanda Richter	Debleena Sinha
Michelle Sands	Barney King	Erica Livingston
Theresa Falls	Duane Mauzey	Irene Hsieh
	Jenny Grodberg	James Wabby
	Michael Swit	Natalie Kennel
	Stephen Thompson	Micheline Awad
		Salman Raza

Many of our instructors went above and beyond expectations. Barney King and Natalie Kennel gave four lectures each; Jenny Grodberg and James Wabby gave three lectures each; Michael Swit, Irene Hsieh, and Duane Mauzey gave two lectures each; Steven Thompson presented a lecture from the United Kingdom from 1:30 to 3:30 am GMT. The Education Committee cannot begin to thank all of our instructors enough for their level of commitment to SDRAN.

SDRAN RAC Preparatory Sessions **would not be possible without the support** of each and every one of these volunteers.

In addition, Jiyoung Heo and Natalie Damrau successfully passed the RAC Devices exam, and were qualified and awarded for the SDRAN RAC Devices Reimbursement program.

## 5. MEMBER RELATIONS

Committee Members:

- Ilham Naili, VP of Member Relations
- Clara Feider

Statistics:

- 62 total new members
- 218 current members (including 9 BOD and 9 lifetime members)

Throughout 2022, the monthly SDRAN programs were maintained online through Zoom. Similar to 2021, SDRAN asked its members through surveys and polls whether they would feel comfortable going back to in-person meetings. While some members appear ready to be back to in-person meetings, the overall trend fluctuated during the year, depending on the spread of new waves of COVID-19 infections. The latest survey of November 2022 reflected that members would be comfortable with going back to in-person meetings in 2023. SDRAN is planning on offering at least a few of its monthly programs in 2023 as in-person meetings

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and is also looking forward to the start of in-person networking events as well as speed networking sessions prior to the monthly seminars.

After a slow start in new memberships, the total number of new SDRAN members ended up being comparable to 2021, although lower than the previous years. This is most likely a reflection of the lack of in-person interactions; therefore, leading to the lack of opportunities to talk to potential new members. With the return of in-person monthly programs and networking events, SDRAN is hopeful to see the number of new members increase in 2023. Nonetheless, SDRAN members continue to be very satisfied with the programs offered by SDRAN throughout the year and continue to rank SDRAN very highly as an organization to join. In surveys, SDRAN members consistently ranked the monthly programs as very valuable with informative presentations from interesting speakers.

For the first time since the start of the pandemic, SDRAN organized an in-person member appreciation event. Unfortunately, due to lack of registrations from members, SDRAN made the decision to cancel the member appreciation event.

## 6. MENTORING

Committee Members:

- Jenny Grodberg - Chair and VP, Mentoring
  - Alessandra Blasina
  - Aniko Hastings
  - Kathy Rangus
  - Kim Walker
  - Laura Guy
  - Olivia Yu
  - Priyanka Apte

The Mentoring Committee achieved the following:

- 9 Mentoring Pairs
  - Mentors:
    - Alessandra Blasina
    - Kathy Rangus
    - Kevin Daly
    - Kim Walker
    - Maria Jose Cortes-Mateos
    - Priyanka Apte
    - Rachel Hernandez
    - Shelley Hall
    - Steve Worcester

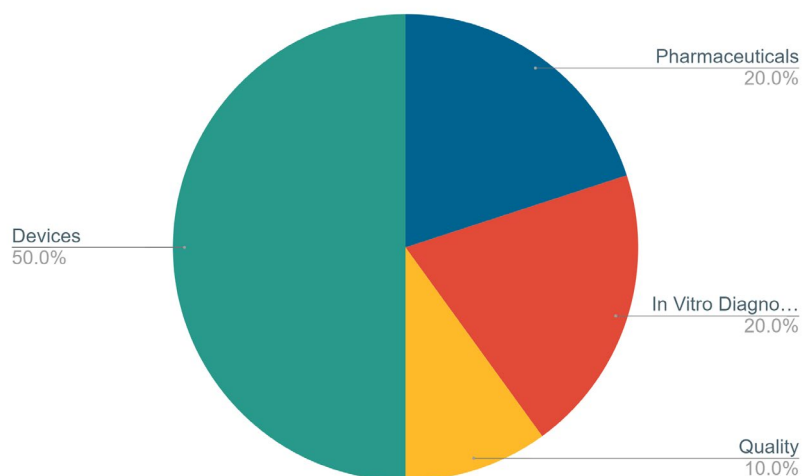
## 7. PROGRAMS

Committee Members:

- Carlos Rojas Torres & Gabriela McCoole, VP of Programs
  - Aniko Hastings
  - Bharathi Hattiangady
  - Erica Livingston
  - Karin Hughes

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**Figure 1: 2022 Program Topic Distribution**



**Table 5: Program Topics in 2022**

Date	Topic	Speaker	No. of Attendees
19 January	How to Effectively Engage with the FDA through the Pre-Sub Process	Isabella Schmitt	42
16 February	Open House <ul style="list-style-type: none"> <li>Breakout Rooms: Ask me (Nearly) Anything</li> <li>Meet University Representatives</li> </ul>	Jenny Grodberg - RA Drugs Erica Livingston - QA Sasi Mudumba - RA Devices Felicia Murray - UCSD Lisa Dowdy - SDSU Susan Bain - USC	30
16 March	How to Throw a Regulatory Tantrum	Allison Komiyama	46
20 April	The Rare Drug Development Landscape: PRIME and Breakthrough Therapies	John Wood	43
18 May	Use of AI in the Regulatory Affairs Space for Peer Review to Enable Global Diagnostic Companies to Obtain Full Approval for IVDR Compliance	Sheila Mahoney Elizabeth Venagro	22
15 June	FDA Meetings, Prepping for Advisory Committee Meetings, and FDA Communication throughout the IND Process	Mary Willhelm	20
20 July	Parallel Scientific Advice: US and EU	Valmik Doshi	32
17 August	Leveraging Social Media and Patient Testimonials for Drug Promotion and	Micheline Awad	15



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Date	Topic	Speaker	No. of Attendees
	Understanding Interactions with Patient and Advocacy Groups		
21 September	iPSPs / PIPs	Jenny Grodberg	32
19 October	IVDR Impacting Companion Diagnostics in the EU	Karin Hughes	15
16 November	What to Expect when Expecting the FDA	Troy Fugate	23

**10 Monthly Program breakdown:**

- Devices - 5
- Drugs - 2
- IVD - 2
- Quality - 1

**Open House:**

Breakout rooms:

- RA Devices
- RA Drugs
- QA

## 8. WEBSITE & COMMUNICATIONS

Committee Members:

- Olivia Yu

EZSignUp Registration System:

- Olivia Yu - Event creation and communications
- Ilham Naili - Membership issues and resolutions
- Daniel Yeh - Financial transactions and audits

## 9. FINANCIALS

**Table 6: Year-End Summary, 2022**

Revenues		Expenditures	
Membership dues	\$8,085.00	Operations (Venue and food)	\$6,073.04 (\$964.84)
Program Income	\$4,054.99	Bank and Merchant fees	\$3,038.85
Job Postings	\$400.00	Speaker Gifts	\$3,950.00
RAC Study Group	\$10,600.00	RAC Books	\$1,226.57
Interest	\$26.46	RAC Reimbursement Award	\$700.00
<b>Total</b>	<b>\$23,166.45</b>	<b>Total</b>	<b>\$14,988.46</b>

**2022 Net revenue: \$8,177.99**



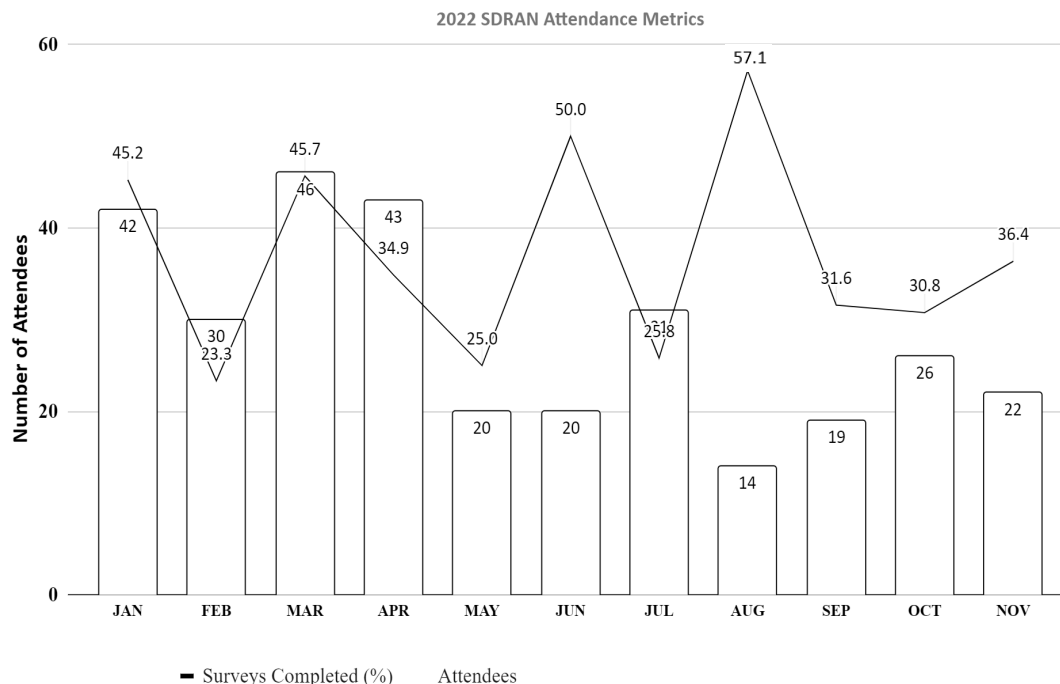
## 10. 2022 SDRAN MONTHLY PROGRAM SURVEY RESULTS

**Table 7: Monthly Program Survey Results**

Programs and Surveys Outcomes	2016	2017	2018	2019	2020	2021	2022
Average Attendance per Program:	57	62	56	44	39	36	28
Average Number of Survey Respondents:	35 (65%)	35 (59%)	13 (22%)	14 (32%)	16 (42%)	13 (39%)	10 (36.9%)
Overall Program Ratings of 4's and 5's:	89%	95%	83%	88%	90%	92%	95%
Overall Speaker Ratings of 4's and 5's:	87%	98%	82%	92%	86%	96%	95%
Overall Networking value of 4's and 5's – With Speed Networking Events rating higher:	75%	76%	67%	NA	NA	NA	NA
Likelihood of recommending SDRAN to others – Yes Responses:	87%	88%	88%	88%	96%	91%	89%
<b>Why you come to SDRAN Meetings:</b>							
• Continuing Education	--	22%	43%	38%	38%	49%	63%
• Networking	--	22%	18%	26%	N/A	N/A	N/A
• Program Topics	--	56%	48%	38%	49%	40%	35%

\* Ratings: 1 Lowest to 5 Highest

**Figure 2: Monthly Program Attendance Metrics**



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## 11. 2022 SDRAN SURVEY RESULTS

- Completed by 2.5 % of BODs, Lifetime Members, Members, & Nonmembers
- Majority are SDRAN Members: 74%
- In the past 12 months, 34% attended 3-11 meetings
  - Majority (45% said topic was relevant & 52% had other reasons)
  - Others included:
    - Link didn't work
    - Most are drug oriented
    - Reduce the number of emails/reminders
    - Want in person meetings
    - Meeting date conflicts with my work schedule.
    - Dislike that it costs money and it's only a webinar. We don't get to interact with any of the attendees and make connections. I want in person events!!
    - Please reduce the number of emails and reminders you send
- 60% who answered survey are in Regulatory Affairs
  - Majority are either in Devices or Pharma/Biotech

**Table 8: Suggested Topics for Monthly Programs**

FDA activities, US and international device regulations, new product innovations	Laboratory developed tests regulations, machine learning/artificial intelligence in medical products, overview of recent FDA guidance documents, overview of warning letter trends & how to proactively address these issues in your quality system, human factors
New Clinical Trial Regulations for EU submissions	Archived availability of previous sessions, FDA hot topics (PDUFA reauthorization, patient-focused drug development, DEI, etc.)
devices	International Regulatory Changes
Regulatory missteps (lessons learned)	QA program basics, skills/knowledge needed to be successful in role and how these can define a career path forward
Regulatory strategy for accelerated drug development. Regulatory requirement for drug repositions. New regulations. Regulatory requirements comparison for drug development among key markets.	Tough question - general FDA and OUS developments. New 510(k) "e-process" steps. Ongoing IVD issues. Professional development.
Tough call for SDRAN - balance between products, compliance, and professional development	IVDR implementation - challenges encountered during Notified Body Review, what were the surprises. Class I, 510(k) exempt devices, what you still need to do. "Recent" (last 2 years) Breakthrough Device

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	Designation experience. EUA - Breathalyzer experience
IVD	NDA submissions (adequately and well-controlled studies), examples of one pivotal study to support an NDA approval
The Covid pandemic sparked concerns about the regulatory process for vaccines. The speed of approval on EUA was not understood, raising many questions. It also created myths that led to refusal to vaccinate and to political discord.  Has and how has the Covid pandemic affected, or not, the Device, Pharma/Biotech industries' regulatory processes?	Drugs and Devices
post approval changes	Any regarding medical devices
Regulatory strategy (US, EU, Health Canada, and ROW)	More about regulatory re-submissions for various countries; where to find regulatory information and where to go to find if it has been updated.

Speakers for Monthly Programs or SDRAN RAC Prep Sessions:

- 2 individuals responded positively and will be contacted by VP.

Individuals willing to volunteer on a Committee:

- 6 individuals responded positively and will be contacted by a VP.

**Table 9: Which Committees are you interested in volunteering for**

Answer Choices	Responses	
Education	66.67%	4
Member Relations	16.67%	1
Mentoring	50.00%	3
Programs	16.67%	1
Website and Communications	16.67%	1
	<b>Answered</b>	<b>6</b>
	<b>Skipped</b>	<b>33</b>

Individuals willing to be mentored for a BOD position:

- 1 individual responded positively and will be contacted

Would you be interested in participating in a half- or full-day workshop?

- 60% responded positively to a half-or full-day workshop

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**Table 10: Topics for a half- or full-day workshop**

Regulatory issues pertaining to managing and conducting research trials.	Anything regarding medical devices/software
devices	Device submissions: IDE, PMA, 510(k), HDE
If virtual	NDA submissions (adequately and well-controlled studies), examples of one pivotal study to support an NDA approval
Anything related to drug or diagnostics development, strategy, new regulations, emerging trends.	Medical Devices but open for other topics
Frank Pokrop used to push for 1/2 day and one-day special topics: (1) submission focused - drug, device, etc. NDA, ANDA, IDE, PMA< 510(k), etc. (2) specialty topics: fundamentals of a clinical trial, QMS, MDSAP, international drug groups (ICH)	Anything regarding Medical Devices
Labeling	Surviving IVD regulatory stuff when you've been thrown in without any training or resource to guide one through re-submissions, QMS management, etc.
Clinical trial strategies and management, pre-market submission strategies and management, quality system building and management	Anything related to AI and regulations

What is your comfort level in attending in-person SDRAN events:

- 47% - Very Comfortable
- 34% - Somewhat comfortable
- 19% - Not comfortable at all

**Table 11: In light of COVID, what has SDRAN done well over the past couple of years?**

Communicate - it is appreciated.	online seminars
Although I have not been able to attend any of your monthly webinars, it appears that SDRAN has done a good job keeping up with presenting new topics and having ongoing discussions that are important to address regulatory issues.	Has maintained continuity of the monthly program.
Continuing to provide monthly programs, including the online member appreciation events	Providing online programs. They are very convenient to attend.
Maintaining the virtual meeting option... thank you as will assist me in recertification this month	Provided zoom availability for meetings, continued with regular meetings
Consistent with monthly meetings	Yes and such options should continue. A hybrid approach would be appreciated.
Everything	Monthly opportunities regardless of the state of the pandemic.

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Continuing the monthly programs online and continuing the RAC Study Groups and Mentoring program.	Kept up a regular schedule of monthly meetings.
Switching from WebEx to zoom was a great move.	The online programs run pretty smoothly; easy to see the slides and hear the presentations, that wasn't always the case. Thank you!
Maintained continuity through active presence in the community, competent leadership, and relevant programs.	online presentations!
Adapting and offering same resources (programs, education, etc.) virtually	Everything
I think that the SDRAN has done an excellent job offering the programs to the community even with all types of restrictions imposed due to the pandemic.	on-line format!

## 12. SUMMARY

The President and the BODs offer a sincere debt of gratitude to our many volunteers, committee members, members, non-members, speakers, and interested third parties for making 2022 another successful year. Our work could not be possible without the support of the community and the hard work of our BOD and committee members. Thank you!

## 13. LIFETIME MEMBERSHIP AWARD

- Jenny Grodberg

## 14. LOOKING AHEAD TO 2023

Nominating Committee:

- Olivia Yu
- Jenny Grodberg
- Sasi Mudumba

2023 Board of Directors

Election closed: 30 November 2022

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**Table 12: 2023 Election Outcome**

Board of Directors for 2023		
Title	Name	Continuing/Elected
President	Olivia Yu	Continuing
<b>President-Elect</b>	<b>Kim Walker</b>	<b>Elected</b>
Past-President	Michelle Sands	Continuing
<b>Secretary</b>	<b>Blake Schouest</b>	<b>Elected</b>
Treasurer	Daniel Yeh	Continuing
VP of Education	Theresa Falls	Continuing
VP of Member Relations	Illham Naili	Continuing
<b>VP of Mentoring</b>	<b>Amanda Richter</b>	<b>Elected</b>
<b>VP of Programs</b>	<b>Jamie Brugnano</b>	<b>Elected</b>
VP of Website & Communications	<b>TBD</b>	

#### **Education Committee**

- RAC Preparatory Sessions - Drugs
- RAC Preparatory Sessions - Devices
- Packages include live online zoom format and pre-recorded sessions, accompanied material (slide decks), and access to RAPS study material discount.

#### **Mentoring Committee**

- Feb: Introduce 2023 Mentoring Program at Open House
- Mar: Mentoring Program Orientation and Mentee/Mentor Applications due
- Apr-Oct: 6-month Mentoring Program

#### **Programs Committee**

- March: Consulting as a Viable Career Path
- April: 5 Most Common Errors in Startups and How to Develop a Regulatory Strategy for Startups
- May: Risk Management according to ISO 24971