



# Introduction to Canadian Association Professional Regulatory Affairs (CAPRA)

January 12, 2009  
Student Relations Committee, CAPRA  
Jennifer (JJ) Wilhelm





- Overview of CAPRA
- A few Items about its History
- Membership Profile
- Current Activities – Benefits of Membership
- Opportunities for Involvement



# Overview



- What is CAPRA?
- It is the premier pharmaceutical regulatory affairs organization in Canada;
- Mission
  - » to provide a forum in which pharmaceutical regulatory affairs professionals can interact and keep abreast of the ever-changing regulatory environment in Canada.



# Overview

## What is CAPRA?

- Non-profit organization
  - » financed via membership and meeting dues
- Non-aligned organization
  - » does not lobby
- Focus
  - » its mission has expanded to include both federal and provincial regulatory affairs for pharmaceuticals, biologicals, medical devices, herbals, veterinary medicines, and radio-pharmaceuticals



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# A few Facts about its History

- Founded in 1981
- 3 people in R&D talking about Regulatory Affairs
- These 3 people talked about the current emphasis on medical affairs. It was agreed that, for political purposes, the proposed organization should:
  - » be local in origin
  - » be inexpensive to attend
  - » meet only in the evenings
  - » discuss regulatory affairs matters only of a non-proprietary nature





## A few Facts about its History

- Original name was Toronto Regulatory Affairs Discussion Group (TRADG)
- Only Regulatory people in brand companies could join!
- First meeting on 26<sup>th</sup> September 1981 with 26 people (dinner and wine) for \$28.
- Monthly meetings with industry speakers
- Resistance from Health Canada as they didn't want to fly speakers to Toronto for a "new" group.
- Opposition from some companies that proprietary information would be discussed.
- Name change in 1989 "Canadian Association of Pharmaceutical Regulatory Affairs"
- Name change in 1997 to current name





## A few Facts about its History

	<b>CAPRA member activities</b>	<b>Reg Submissions</b>	<b>Ave HC review time:</b>
1981 – 1985	TRADG – 28 members attending dinner meetings and workshops	5 part submission (paper only)	37 months
1986 – 1990	TRADG – 150 members attending dinner meetings, NOC publication and education day	5 part submission (paper only); Submission Cert & HPB3011	35 months
1991 – 1995	CAPRA – 300 members attending dinner meetings, NOC publication, education day and symposium	5 part submission WordPerfect Templates	36 months
1996 – 2000	500 members attending dinner meetings, NOC publication, education day and symposium	5 part submission Submission Fees	19 months
2001 – 2005	CAPRA – 900+ members attending dinner meetings, NOC publication, education day and symposium (2)	5 module submission Paper & Electronic ICH and CTD WP and Word	24 months



# A few Facts about its History

- In 2004, CAPRA was incorporated
- By-laws for the conduct of the organization ([www.capra.ca](http://www.capra.ca))
  - (a) to provide a forum for RA professionals in the health care products sector to exchange non-proprietary experiences of common interest;
  - (b) to develop a professional identity and recognition for RA professionals in the health care product RA field;
  - (c) to provide opportunities for training and development of RA professionals;
  - (d) to provide and disseminate information and interpretations related to regulatory policies, including publication of magazines, periodicals and other information;





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# Membership Profile

- Membership has grown to 1,000+ professionals
- All activities are led by volunteers!!
- Consists of:
  - General members
  - Board of Directors (min of 5 and max of 15)
    - Consists of Chair, Vice Chair, Treasurer, Corporate Secretary, Directors and Officers
  - Several committees including:  
Finance; Website; Health Canada Liaison; Symposia; Education Day; Dinner Meetings; Policies; Elections; Publications; Student Relations; etc





# Membership Profile

## Survey of Membership

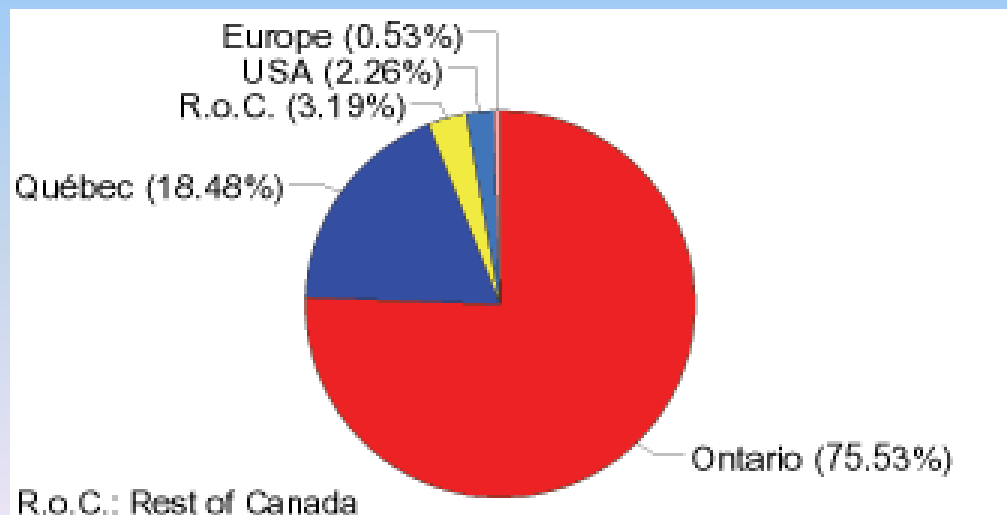
- Demographics
- Educational Background
- Number of years experience and title
- Type of Company
- Size of RA department
- Area of Focus
  - Type of products
  - jurisdictions
- Other memberships



# Membership Profile

## Survey of Membership

- Gender:
  - Male 28%: Female 72%
- Geographical Distribution:





# Membership Profile

Degree Type	Yes (%)	No (%)	Total
Bachelor's	176 (94%)	12 (6%)	188
College	93 (53%)	83 (47%)	176
Master's	55 (31%)	120 (69%)	175
Ph.D.	19 (11%)	148 (89%)	167
Pharm D	4 (2%)	161 (98%)	165
MD or DVM	0	-	-
Other	22 (13%)	142 (87%)	164



# Membership Profile

	<b>Yrs Related Experience</b>	<b>Yrs RA Experience</b>
1	11 (6%)	16 (9%)
2	6 (3%)	15 (8%)
3	8 (4%)	17 (9%)
4	9 (5%)	10 (5%)
5	19 (10%)	19 (10%)
6	10 (5%)	18 (10%)
7	8 (4%)	12 (6%)
8	10 (5%)	8 (4%)
9	9 (5%)	13 (7%)
10+	97 (52%)	59 (32%)
Total Respondents	187 (100%)	187 (100%)



# Membership Profile

<b>Position Title</b>	<b>% (N)</b>
Student	3% (5)
Coordinator	3% (6)
Associate /Specialist	36% (62)
Project Leader /Project Manager / Senior Associate	22% (39)
Manager	25% (43)
Director	13% (23)
Vice President	3% (5)
CEO/President	3% (6)
Consultant	13% (22)



# Membership Profile

Type of Company	N (%)	Type of Company	N (%)
Industry - Large Pharmaceutical	96 (51%)	Trade/Professional Organization	2 (1%)
Industry - Small Pharmaceutical	40 (21%)	Legal	1 (1%)
Consulting Services	21 (11%)	Publishers/Editorial	1 (1%)
Industry - Biotech	14 (7%)	Government	1 (1%)
Industry - Medical Device	6 (3%)	Validation/Data Processing Services	1 (1%)
Industry - CRO	4 (2%)	Hospital/Medical Practice; Translations Services; IT/Software Solutions; Academic Institution	0 (0%)
Recruitment	1 (1%)	Total Respondents:	188 (100%)



# Membership Profile

<b>Number of Employees</b>	<b>Company</b>	<b>Regulatory Department</b>
1-5	15 (8%)	60 (33%)
5-10	3 (2%)	26 (14%)
10-25	3 (2%)	44 (24%)
25-50	11 (6%)	29 (16%)
50-100	14 (8%)	18 (10%)
100-500	41 (22%)	5 (3%)
500+	98 (53%)	1 (1%)
Total	185 (100%)	183 (100%)



# Membership Profile

<b>Types of Products</b>	<b>Yes (%)</b>	<b>No (%)</b>	<b>Total</b>
<b>Pharmaceutical Drugs</b>	178 (95%)	10 (5%)	188
<b>Combination Products</b>	134 (74%)	47 (26%)	181
<b>Biologics/ Biotech</b>	129 (72%)	51 (28%)	180
<b>Medical Devices</b>	86 (48%)	95 (52%)	181
<b>Cosmetics/ NHPs</b>	62 (35%)	116 (65%)	178
<b>Nutritional Products</b>	58 (32%)	121 (68%)	179
<b>Veterinary Medicines</b>	14 (8%)	162 (92%)	176



# Membership Profile

<b>Jurisdiction(s)</b>	<b>Yes (%)</b>	<b>No (%)</b>	<b>Total</b>
Canada	186 (99%)	1 (1%)	187
US	135 (75%)	46 (25%)	181
EU Europe	126 (69%)	56 (31%)	182
Worldwide	94 (53%)	82 (47%)	176
Australia/New Zealand	90 (51%)	88 (49%)	178
Asia - Japan	45 (26%)	129 (74%)	174
Latin America	44 (25%)	132 (75%)	176
Asia - China	43 (24%)	134 (76%)	177



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# Benefits of CAPRA Membership

[www.capra.ca](http://www.capra.ca)

## What can you access without a membership?

- Access career opportunities;
- Access proposed schedule of meetings and conferences;
- Access information on how to become a member;
- Review list of consultants.





# Benefits of CAPRA Membership

- Membership fee is only \$49 (per year)
- The membership fee is the same, no matter when during the membership year you join.
- Membership is not transferable, and remains with the member regardless of who paid for it.
  - Hint: use your home address for mailings
- To join CAPRA/ACPR as a new member
  - fill out the membership application form on website ([www.capra.ca](http://www.capra.ca))





## Benefits of CAPRA Membership

- Networking with other Regulatory Affairs professionals;
- Keeping abreast of recent Health Canada initiatives;
- Attend meetings (at reduced rates or as a volunteer) and ask questions to Health Canada;
- Access to membership database;
- Vote in Annual General Meeting;
- Vote for Board of Directors;
- Participate in surveys;





# Benefits of CAPRA Membership

## Up to Date Regulatory Information!!

- Receive quarterly magazine called “The News of Course” (or “The N.O.C”);
- Receive ~bi-weekly e-mails with information about upcoming events;
- Access presentations from meetings;
- Attend Education Day for reduced price;
- Attend symposia for reduced price;
- Attend monthly evening meetings for reduced price;
- Keep your membership even if you change jobs.





# Benefits of CAPRA Membership

- Examples of meeting topics
  - Updates from Product Licensing at NHPD
  - Bioequivalence/Biosimilarity
  - Good Review Practices: SOPs and S&E
  - Post Notice of Compliance Changes
  - Creating Submission Ready e-CTD Documents
  - Complying with Health Canada's Guidelines for Transportation of Drug Products



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# Opportunities for Involvement

- *Volunteers are always needed!!!!*
  - » Education day & Symposium
  - » Publications and editor  
(Robert.Wong@novopharm.com)
  - » Dinner Meetings
  - » Marketing
  - » Website
  - » Other





# Opportunities for Involvement

It Benefits YOU!

- Meet regularly with industry peers,
- Meet with Health Canada at committee dinners,
- Name/face recognition through NOC article writing,
- Learn about the industry and potential employers!





## Questions for YoU

- How many people here have gone on the CAPRA website?
  - How often?
  - Would a student web page interest you?
- Is anyone here a CAPRA member?
- Have you attended a dinner meeting before? If yes, what prompted you to do so?
- Are you a member of other organizations?





# Questions and Answers

- Questions???
- Answers!!!



***Thank You for Your Attention:***

***contact information:  
Jennifer (JJ) Wilhelm  
jj.wilhelm@videotron.ca***