

CANADIAN ASSOCIATION OF RADIOPHARMACEUTICAL SCIENTISTS

Newsletter



March 2019

www.RadiopharmacyCanada.com

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Justin Hicks

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Shaun Ramdhany

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A message from the president

It is with great pride that I assume the role of president for the Canadian Association of Radiopharmaceutical Scientists for the next two years. We have come far – with strong leadership and dedicated persistent talent. We are a strong and growing society, but we still have much to do. I welcome the challenge. It's time to take the Society to the next level. Here is my plan:

- To be more effective, we need to grow in membership. I ask that we all look to the future and imagine what we can do for the Canadian Radiopharmaceutical community and the patients we serve with more members working to develop the profession through collaboration, mentorship, and training of young scientists. Identify and invite your peers and young professionals to join CARS.
- We will continue to build the reputation of radiopharmaceutical professionals through our work with the Canadian Association of Nuclear Medicine (CANM) as well as Universities across the country. We expect our work with these organizations to be the key to the recognition of CARS.

I hope you will join me in this mission. It will happen with the strategic focus of a dedicated, professional force from our CARS members.

In this newsletter, you will find an introduction to each of the great individuals that are on the CARS executive this term. We have a very diverse executive, with people actively working as radiopharmacists, radiochemists, academic researchers as well as within the quality assurance and radiopharmaceutical corporate business area. Please make sure to reach out to any of us if you have suggestions, need information, help to make a connection within the community or anything else for that matter.

With best regards,

Jan Andersson, PhD
President, Canadian Association of Radiopharmaceutical Scientists



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CARS 2019 EXECUTIVE

President Jan Andersson, PhD



Director, Senior radiochemist



Edmonton Radiopharmaceutical Centre &
Cyclotron, Alberta Health Services,
Diagnostic Imaging, Edmonton, AB

My name is Jan Andersson, and I am currently the director and senior radiochemist at Edmonton Radiopharmaceutical Centre (ERC), Alberta Health Services. After graduating with a MSc. in chemical engineering from Uppsala University, Sweden, I was fortunate to get an opportunity to work in the very productive Farde / Halldin brain-imaging group at Karolinska Institutet, Stockholm, Sweden. After completing a Ph.D. in radiochemistry/medical sciences, I took on the role as head of production and helped to implement a GMP system from the ground which was a great learning experience.

A chance encounter with John Wilson from the University of Alberta at ISRS in Amsterdam, made a move to Canada an actuality. I worked for six years as a radiochemistry researcher and head of quality control at the Department of Oncology, the University of Alberta in Edmonton.

My interest in radiopharmaceuticals was initiated by radioligand development work for psychiatric disorders and its role in drug development. I especially found the rapid results both from production and scans very satisfying.

Also, research within radiochemistry / imaging is a true interdisciplinary field, which is something I have always enjoyed. Radioligand development is still a big interest of mine, and more recently cyclotron production, SPECT radioligands as well as GMP and the regulatory portion of radiopharmaceutical manufacturing have captured my interest (and work hours).

As a proud father of three sons, I am fortunate to get to go skiing, play hockey, soccer, golf, tennis and build Lego in my spare time, all things I enjoy greatly. My opinion is that CARS has a very strong member base with a lot of expertise, as a CARS executive member I hope to contribute to raising the profile of CARS, utilize the inherent expertise, and increase the membership.



CARS 2019 EXECUTIVE

President-Elect Justin Hicks



Lawson Health Research
Institute,

London ON

My name is Justin Hicks and I'm the current President-Elect of CARS. Currently, a research scientist at Lawson Health Research Institute and assistant professor at Western University in London, ON, my efforts are focused on cherry picking promising brain PET probes for translation to clinical trials while also dabbling into novel PET probe development. My primary expertise is short-lived PET isotope radiochemistry, mostly ^{11}C and ^{18}F but I have also recently validated production of $^{13}\text{N-NH}_3$ and $^{15}\text{O-H}_2\text{O}$ for clinical trials. Our cyclotron facility supplies southern Ontario with six different probes with many more undergoing translation.

After completing graduate studies at McMaster University (MSc in $^{99\text{m}}\text{Tc}$ purification) and the University of Toronto (Ph.D. in ^{11}C NeuroPET), I've learned an immense amount about GMP, CTA, quality systems, and radiopharmaceutical supply chains. Nevertheless, it is a continuous learning curve where knowledge translation and networking play a predominant role. This is where CaRS can be integral to growth in our small field. I hope to build upon my tenure as secretary and grow our social media presence as a tool to foster collaboration across Canadian radiopharmacies.

Outside of the lab, I'm usually playing or reading with my two daughters (4 and 2) and son (6 months) or working on DIY house projects with my wife. This summer I hope to instill my love for camping and cycling into my children and introduce them to the outdoor wonders our nation has to offer.

Radiopharmacy is a small community. Communication is the key to achieving our common goals. Reaching out to radiopharmacies, nuclear medicine departments, and aligned universities across Canada to increase awareness of CaRS will facilitate new collaborations and knowledge sharing.

I look forward to building new and strengthening old relationships to cement Canada as a world leader in radiopharmaceutical science.



CARS 2019 EXECUTIVE

Past President Shaun Ramdhany



I consider myself fortunate to be practicing in a field of science, which has been my professional passion over the past 18 years.

After graduating from Pharmacy School at the University of Witwatersrand, Johannesburg, South Africa; I specialized in Nuclear Pharmacy with Syncor International (the predecessor of Cardinal Health NPS). I gained considerable experience in centralized nuclear pharmacy operations while managing the Syncor facility in, South Africa.

In 2007, I was provided a life-changing opportunity to emigrate to Canada and lead the Radiopharmacy Department at Toronto General Hospital. During this time, I've had the good fortune of working with an expert Nuclear Medicine team at the Joint Department of Medical Imaging at UHN, including pre-eminent Radiopharmacy scientists like Prof. Raymond Reilly (University of Toronto- LMIR).

TGH was an opportunity to broaden my scientific scope in the fields of cGMP Radiopharmacy, Radio-Immunotherapy, and cutting-edge clinical trial & drug development work. I was also an invited guest-lecturer at the Michener Institute of Applied Health Sciences and University of Toronto (Faculty of Pharmacy) where I relished providing academic and practical training to future Nuclear Medicine professionals. In 2008, I had gained accreditation as a Board Certified Nuclear pharmacist in 2008, through the US Board of Pharmaceutical Specialties and will be recertifying by exam at the end of this year.

I subsequently transitioned back to commercial Radiopharmacy operations where I've had the opportunity to work with Fortune-500 companies e.g. GE Healthcare (Medical Diagnostics) and Cardinal Health (Nuclear Pharmacy Services). I am currently Vice President of Scientific Affairs at ISOLOGIC Innovative Radiopharmaceuticals, leading a network of seven PET and SPECT centralized Radiopharmacy operations across Canada.



CARS 2019 EXECUTIVE

Secretary
Shannon Colbert, M.Sc



President and Principal
Consultant



Simple Compliance Solutions
Ltd.

Saskatoon, SK, Canada

My name is Shannon Colbert, and I am the current Secretary for CARS. I am the President and Principal Consultant at Simple Compliance Solutions Ltd. providing consulting services to pharmaceutical manufacturers in need of regulatory and quality system expertise.

I have worked in pharmaceutical quality and regulatory affairs, including radiopharmaceuticals, since graduating from the University of Saskatchewan with MSc Degree. in physiology. I have had much success applying my education and experience over these years into GMP/GPP quality system design, manufacturing facility commissioning/validation, quality control method development and validation, CTA and NDS project management.

The intricacies of managing a quality system that matches the on-demand manufacturing needs of radiopharmaceuticals are indeed very challenging. It is my honor to help my clients in finding a custom, simple solution to achieving the highest level of control and quality in their radiopharmacies. I am continuously impressed by the hard work and dedication of radiopharmaceutical scientists, knowing the enormous impact your work makes in the lives of patients requiring nuclear medicine. This keeps me committed to leading continuous improvement efforts to expand and provide consistency in the supply of radiopharmaceuticals.

On a more personal level, I have a son and daughter (ages 11 and 8), who challenge me and keep me very busy. My favorite past time is finding and trying new exotic recipes, and I love dancing!!! The winter in Saskatchewan is unbearable right now... I am very thankful for working indoors. However, during the spring and summer, you would be hard pressed to find me anywhere but swimming in a beautiful Saskatchewan lake or in my yard gardening.

I am very happy to have stepped into the role of Secretary this year from serving as Editor/Member-at-Large for the past 2 years. Your new executive is motivated to make a value-added impact unifying this small radiopharmaceutical community, bridging gaps in regulatory understanding and research collaborations. I look forward to working for you, facilitating relationships, creating an even playing field for radiopharmaceutical scientists in Canada.



CARS 2019 EXECUTIVE

Treasurer Vincent Bouvet, Ph.D



Radiochemist and Clinical
Assistant Professor



Eastern Health,
St John's, NL

I am the radiochemist in charge of the radiopharmaceutical (RP) clinical production at Eastern Health, St John's. I also hold a clinical assistant professor appointment with Memorial University of Newfoundland (MUN). The overarching focus of my research group is to bring to patients cutting edge diagnosis and therapy for Cancer and Neurodegenerative Diseases and in the process expose and train students and Nuclear Energy Workers (NEWs) to this exciting multidisciplinary field of radiopharmaceutical sciences. Our present efforts are presently geared toward the clinical implementation of novel RPs (^{68}Ga -PSMA and ^{68}Ga -DOTATATE) and the development of in-vivo radiolabeling techniques which to my opinion are 2 aspects that will rapidly lead to improved diagnosis and treatment for our patients.

After graduating with MSc. In Organic Chemistry from the University of Orléans, France, I completed a Ph.D. in Medicinal Chemistry, in Ottawa, ON, Canada. In 2006, I joined the group of Dr. Bundle and Dr. Lowary for a Post Doctoral Fellowship focusing on the design and synthesis of carbohydrate-based vaccine at the University of Alberta, AB. Following this exciting experience, I joined in 2008, Dr. Frank Wuest research group where I specialized in radiochemistry, targetry and GMP clinical regulations. In 2016 I took on the role of radiochemist at the St John's Health Sciences Centre. My objectives are presently two folds 1- contributing with the help of our clinical team to implement our GMP radiopharmaceutical production centre from the ground up and 2- developing a collaborative network of researchers within MUN to create a successful radiopharmaceutical sciences research program in St John's.

CARS is to my opinion the ideal association for our community to share ideas, protocols and productions strategies. I am looking forward to work with our board to implement the vision of an unified community which will collaborate to overcome the different regulatory and budgetary challenges of our field.

As the father of a rambunctious 6-year-old son, I enjoy our family time and the opportunities we get to travel over the world together. During my "abundant" free time, I also enjoy playing Hockey, Squash and boardgames.



CARS 2019 EXECUTIVE

**Editor/Member at
Large**
Lidia Matei, Ph.D



Corporate Business
Officer



Sylvia Fedoruk Canadian
Centre for Nuclear
Innovations,

Saskatoon, SK

My career in radiochemistry expands over 23 years starting with the completion of a B.Sc. degree in Radiochemistry followed by a second degree B.Sc. in Biochemistry at the University of Bucharest, Romania. I pursued my career path as a scientist at the Radioisotope Production Centre of the Romanian largest Nuclear Physics Institute. I become involved in the production of radiopharmaceuticals for three major product lines Mo/Tc-99m generators, Na[I-131] capsules and oral solution. In my role as Production Coordinator, I led the projects for GMP implementation on Na[I-131] product lines and obtained the Market Authorizations for these products.

On the scientific side, I have worked for seven years on the synthesis of labeled compounds with tritium and their application in life sciences leading to M.Sc degree in Chemistry and culminating with my Ph. D thesis defended in 2009.

Two years later, I joined the group lead by Prof. Brigitte Guerin at the University of Sherbrooke as a postdoctoral fellow in the exciting project of cyclotron produced Tc-99m part of NISP. My passion in applied nuclear chemistry had another direction as R&D radiochemist at the cyclotron division of Best Theratronics in Ottawa/ For three years, I learned elements of cyclotron design and got in-depth knowledge of targetry development. Also, I have continued the work on Tc-99m produced by cyclotron by coordinating a few industrial R&D projects. The world of radiochemistry is infinite, a few years later I moved to Saskatoon part of the team at Canadian Isotope Innovations. In my role, I worked on the development of linac produced radioisotopes and on the processing low specific activity Mo-99, extraction of pertechnetate and on processing, extraction, and purification of linac Cu-67.

The work on a start-up, a spin-off company, introduced me into a new environment, the development of business relations and collaborative research in the industry. In 2017, I started to work on my parallel career and enrich my business skills at Edwards School of Business, University of Saskatchewan. Recently, my career reached a peak in my new role of Corporate Business Officer at Fedoruk Centre.

In my spare time, I serve the European Commission as Expert Evaluator for Research Projects or enjoy a great movie night with my family. As Editor/Member at Large of CARS your interests will be served by creating a live spirit. I will help you in conveying your messages and have your voice heard. Please join me on this great journey, and I will be happy to serve you.



NEWS

<p>Shortages Coletech (Mebrofenin) Supply</p> <p>Shortage active, expected end date April 04, 2019</p>	<p>Choletec Canadian product has been unavailable in Canada and US labeled supply was allowed in by Health Canada to bridge in October 2018. Currently, the product is backordered due to logistical delays at the contract manufacturer's level. The previously authorized quantity of the US labeled product has been depleted.</p> <p>A limited quantity of the US labeled product has been authorized by Health Canada for distribution nationally waiting for the Canadian release in Feb 2019 (refer to the anticipated shortage resolution date).</p> <p>https://www.drugshortagescanada.ca/shortage/45374</p>
<p>Updates on Mo-99 supply</p> <p>No current shortages</p>	<p>Cessation of Mo-99 Production Activities by NTP Radioisotopes Ltd. (NTP) Update ANSTO Press Release – OPAL reactor – Update, Brussels, 21 January 2019</p> <p>The AIPES Security of Supply working Group (SoS WG) composed of Mo-99 processors, research reactors, and generator manufacturers received an update from NTP Radioisotopes (South Africa) on January 19, 2019, concerning its Mo-99 and I-131 production activities.</p> <p>NTP recently was authorized by the National Nuclear Regulator of South Africa to continue to perform routine Mo-99 production runs at around 40% of its capacity through the end of February 2019, which is the same level that has occurred since NTP returned to production in late November 2018. No Mo-99 or I-131 shortages have been experienced since NTP returned to service and none is anticipated in this upcoming period.</p> <p>NTP will update AIPES in late February regarding its Mo-99 and I-131 production activities.</p>
<p>Regulatory</p> <p>EMA released the guideline on the non-clinical requirements for radiopharmaceuticals</p>	<p>The European Medicine Agency (EMA) has issued the guideline on the non-clinical requirements for the radiopharmaceuticals. The document provides details regarding the data that must be submitted for the non-radioactive part of the radiopharmaceuticals. The guideline focuses on the non-clinical testing requirements for radiopharmaceuticals and is available for consultation and open for comments until June 30, 2019. If you are interested in taking a look on the European regulatory framework, the document is accessible if you follow the link below.</p> <p>https://www.ema.europa.eu/documents/scientific-guideline/draft-guideline-non-clinical-requirements-radiopharmaceuticals-first-version_en.pdf</p>

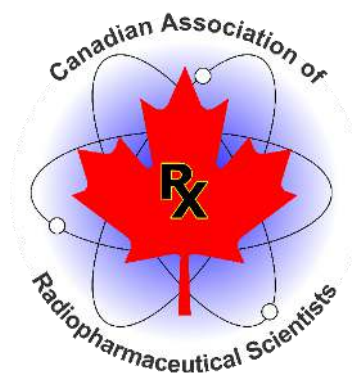
<p style="text-align: center;">Our selection</p> <p style="text-align: center;">Upcoming scientific events 2109</p>	<p>11th International Symposium on Alpha Therapy (TAT-11) April -01-05, Ottawa, Ontario</p> <p>The 11th International Symposium on Targeted-Alpha-Therapy (TAT11) will provide information on the newest developments in preclinical studies, clinical experiences, dosimetry and instrumentation, quality assurance, regulatory, targeting, radiochemistry and nuclide production and supply. Participate in the latest discussions, scientific exchange and in focused networking with industry leaders from around the world.</p> <p>https://www.tat11.com/</p> <p>SNMMI 2019 Annual Meeting, June 22-25, 2019, Anaheim, California</p> <p>The Canadian scientific achievements will be celebrated this year at SNMMI 2019. Canada is the highlighted country, and our radiopharmaceutical and nuclear medicine community will have the opportunity to present the latest Canadian developments in the industry.</p> <p>http://www.snmmi.org/AM/index.aspx?ItemNumber=12337</p> <p>WMIC-2019 World Molecular Imaging Congress, September 4-7, 2019 Montreal, Canada</p> <p>WMIC 2019 provides a unique platform for scientists and clinicians to present and follow cutting-edge advances in molecular imaging. General abstract submission closes April 10, 2019.</p> <p>http://www.wmis.org/2019-wmic/</p> <p>IAEA- International Symposium on Trends in Radiopharmaceuticals (ISTR-2019), October 28-November 01, 2019, Vienna, Austria</p> <p>The International Symposium on Trends in Radiopharmaceuticals, ISTR-2019, will provide scientists and professionals working in the fields of production of radioisotopes and radiopharmaceuticals an international forum for discussing the most recent developments in the field. Various topics will be covered during the Symposium including development, production, and uses of diagnostic, therapeutic, and theranostic radioisotopes and radiopharmaceuticals, as well as regulatory and licensing issues related to their production. Education, certification and training methodologies will also be addressed.</p> <p>https://www.iaea.org/events/istr-2019</p>
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LETTER FROM THE EDITOR

Dear members:

We hope that the winter is not too harsh on you this year. We are happy to present you the first edition of CARS newsletter of 2019.

In this edition, you have been introduced to our new team of executives recently elected during the last Annual General Meeting held during the Health Canada Regulatory Workshop on Radiopharmaceuticals last November. The community is informed about the current status on shortages regarding drug products with impact on radiopharmaceuticals. Our members have the opportunity to gather together at the future scientific events such as at the Targeted Alpha Therapy (TAT-11) or relatively soon Annual Meeting of SNMMI in Anaheim, California. The International Atomic Energy Agency will host the largest event of this year in the radiopharmaceutical industry (ISTR-19) in Vienna.



During the last years, the Canadian radiopharmaceutical community has evolved in a different amazing direction. New facilities were built and more production and scientific capacity is now available in Canada. In the future editions, you will be guided through the new facilities, and together we will have the opportunity to connect ourselves and create a new scientific relationship. We will keep you updated with the latest news in the industry regarding drug shortages, regulatory actions or scientific events. Our purpose is to expand our community and to attract dedicated members who are willing to share their passion for being a radiopharmaceutical scientist.

As always please ensure your member information is up to date (email, mailing address, phone number(s)) and registration dues are paid up so that we keep you informed of activity in our radiopharma community. We also encourage you to reach out to us with recommendations to help you get the most out of your membership. Our motivation is to provide value for our members and share best practice guidance to our Radiopharmaceutical community.

Thank you for being a member of the Canadian Association of Radiopharmaceutical Scientists!

Sincerely,
Lidia Matei

Editor/Member-at-Large (CARS)



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