

Industrial Pharmacy Residency Program

Terms of Reference

ADMINISTERED BY

LESLIE DAN FACULTY OF PHARMACY University of Toronto

With participating companies (Updated August 26, 2019):

Allergan Inc.
Amgen Canada
Astellas Pharma Canada Inc.
Bayer Inc.
Biogen Idec
Eli Lilly Canada Inc.
GlaxoSmithKline Inc.
Hoffmann-La Roche Ltd.
Novo Nordisk
Purdue Pharma (Canada)
Sanofi Genzyme
Sanofi Pasteur

The participating companies reserve the right to change or remove their offering of a residency program at any time. Applicants should check the most recent list of companies and positions on the website: https://pharmacy.utoronto.ca/programs-and-admissions/residency-programs/industrial-pharmacy-residency-program/.

For further information, please contact:

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I. DEFINITION AND PARTICIPATING COMPANIES

The Industrial Pharmacy Residency Program is a one-year program administered by the Leslie Dan Faculty of Pharmacy, University of Toronto in cooperation with participating pharmaceutical companies as listed in this document and on the website.

II. ELIGIBILITY

- 1. An applicant for the position of Industrial Pharmacy Resident must be a pharmacist or a student in the final year of an undergraduate program leading to a recognized university degree in pharmacy. *In the latter category, an applicant must complete all pharmacy degree requirements before starting the residency.*
- 2. An applicant for the specialty program will be required to have had some pharmacy experience such as Industrial Pharmacy, Community Pharmacy, Hospital Pharmacy or Research.
- 3. An applicant must have graduated, within the previous five years from the application year, with a recognized professional (practice) degree in pharmacy from an approved university. (Approved programs will be those accredited within Canada by <u>CCAPP</u> or within the USA by <u>ACPE</u>. Other programs may be approved, based on review of applicant's university transcripts by the Residency Coordinator, to determine comparability with a Canadian undergraduate pharmacy practice degree.)
- 4. Preferences: A license to practice pharmacy is not mandatory, but recommended. Previous industrial work experience is not required. Applicants who have been

- employed more than three years in Industrial Pharmacy will ordinarily not be eligible for the program.
- 5. Canadian citizenship and permanent resident status will be given priority.

Note: this is an educational residency program, it is not an application for a position with a pharmaceutical company.

III. APPLICATION PROCEDURE

- 1. Applicants should review information provided by the specific companies, paying particular attention to the abilities and characteristics required. This information may be found on the website.
- 2. Applicants must follow the Application Process. (See <u>website</u> for the most current and updated application process and specifics of how and where to submit information.) **Steps outlined in 3 and 4 must be completed between September 1 and October 15,** for residencies beginning the following September.
- 3. The following are the steps to anticipate. (See <u>website</u> for the most current and updated information.) Applicants should plan to submit the following information:
 - a) a completed Application, including the names of two references
 - b) reasons for wanting to enroll in the Industrial Pharmacy Residency Program (letter of intent)
 - c) a resume/CV- ensure to include:
 - University education, including pre-pharmacy, pharmacy, dates and degrees
 - Honors, Awards, including academic and extra-curricular, with dates
 - Licensure status in pharmacy, including jurisdiction and date registered
 - Employment, including pharmacy-related positions and/or pharmacy program placements; list at least three most recent positions with dates
 - Organization membership, offices held (professional and others)
 - Other interests, accomplishments or activities in which the applicant has participated
 - d) a PDF copy of official or unofficial transcripts from university pharmacy program (verification may be required)
 - e) an indication of the companies to which the applicant is applying
 - f) an optional cover letter specific to each company to which the applicant has applied. Letter should include the rationale for seeking a residency at that particular company and the specialty area.

The office of the Industrial Pharmacy Residency Program will check each application submitted for completeness of parts a) to d), by Sept 30; if satisfactory, applicants will then need to choose the companies they wish to apply to by October 15 (parts e and f).

- 4. The applicant will be required to pay an application fee.
- 5. During the last two weeks of October, the Faculty will securely provide the applicant's

package to the designated representatives of those companies the applicant has selected.

- 6. Applicants selected for interviews will be contacted by the company to schedule appointments during November and December.
- 7. The company supervisor(s) will make offer-of-residency decisions and contact the applicants accordingly. This should occur on a specific date (to be posted) in January.
- 8. If an applicant has not been contacted by the above date then the applicant should assume that his or her application was unsuccessful for the initial offers. There may be opportunities for further offers should any initial ones be declined.
- 9. The successful applicant will sign a confirmation letter/agreement, provided by the company supervisor, that they have accepted a residency at the company.
- 10. The company supervisor will send an email to the Residency Coordinator to confirm the name(s) of applicants who have accepted positions. This step should occur on or before January 31, or as posted.
- 11. The Faculty will contact successful residents asking for permission to publish their names in the Terms of Reference and to gather other relevant information.
- 12. Applicants normally start the residency on Sept 1st. A different date may be negotiated with the company but will not normally be beyond Sept 30th.

IV. STARTING DATES

Normally, the resident will begin the program no earlier than **September 1** and no later than **Sept 30**.

The normal starting date for applicants who have completed all academic requirements is September following their acceptance by the participating company. An alternate starting date may be selected if agreeable by both the resident and the supervisor of the participating company, provided that the applicant has completed all academic requirements including examinations, clinical and other rotations, and projects.

V. OBJECTIVES

Upon completion of the **Industrial Pharmacy Residency Program**, all residents will be able to:

- Apply a systematic approach to the investigation, analysis and response to an identified issue in Industrial Pharmacy
- Prepare and deliver audience–appropriate oral and written reports

Upon completion of the **General Industrial Pharmacy Residency Program**, the resident will be able to:

• Demonstrate a thorough understanding of several facets of Industrial Pharmacy

- Describe the interrelationships among the various divisions within a pharmaceutical company
- Demonstrate in-depth understanding of at least one functional area within a pharmaceutical company

Upon completion of the **Specialty Industrial Pharmacy Residency Program**, the resident will be able to:

- Demonstrate sufficient competence (knowledge and skills) in a specialized area or areas of Industrial Pharmacy
- Demonstrate a general understanding of many areas of Industrial Pharmacy

VI. PROGRAM

- 1. The intention of the general residency is to educate the resident about different areas of Industrial Pharmacy and to provide an opportunity to gain industrial experience. The specialty residency enables the resident to focus their activities on one or two particular areas of interest.
- 2. The general residency is composed of core rotations through many of the company's departments, thereby ensuring broad exposure to multiple facets of Industrial Pharmacy. In addition, the resident will have the opportunity to carry out a major project which will develop the resident's research and investigative skills and the preparation and writing of reports. Finally, the resident will be able to develop their special areas of interest in conjunction with those of the company in the elective portion of the program.
- 3. The program must have an encompassing base which will give the resident the requisite exposure to ensure that the year of special study has a definite and positive value. This value comes in part from the educational background and insight of the pharmacy resident and the overview which the resident receives in areas such as research, manufacturing, quality assurance, clinical testing, regulatory affairs, marketing, sale of pharmaceuticals, medical information, post marketing surveillance, managed care, drug safety and pharmacoeconomics. A resident should understand how all these company activities interrelate and the impact they have on the various health professions. The program consists of practical experience, including exposure to the various approaches to solving problems. Finally, the resident should complete the program with a tangible gain in skills and knowledge demonstrated by an ability to perform identifiable tasks.

VII. INFORMATION FOR THE GENERAL RESIDENCY

NOTE: this general residency is not currently offered

In order to provide flexibility while ensuring an encompassing base for the program, a six-month core consisting of at least six core rotations and a major project, plus six months of elective activities are required to be provided by the participating companies to form the twelve month program.

1. OUTLINE OF PROGRAM

Time (months)	Activity		
	Core Rotations		
0.5	Product formulation/reformulation –develop		
0.5	Production – purchasing raw materials; inventory control; scheduling; packaging, actual hands-on production.		
0.5	Ouality control – raw materials; finished products; stability testing; self-inspection; recall program.		
0.5	Product marketing – strategy; programs.		
0.5	Clinical research		
0.5	Regulatory affairs		
0.5	Drug information		
0.5	Sales training		
0.5	Managed care		
0.5	Pharmacoeconomics		
3.0 Major proj	3.0 Major project		
<u>6.0</u>	Total core program		
<u>6.0</u>	Elective Activities		
12.0	Total program		

- 2. Some definitions of the above terms are provided in <u>Appendix IV</u>.
- 3. The company supervisor will provide the resident with a list of the goals and objectives for each core rotation and each elective activity. The department head or delegate in each of the above rotations will be requested by the company supervisor to provide a brief report on the involvement of the resident in the department.
- 4. The resident will submit reports in each rotation to the company supervisor and a final summary report along with the project report to the Core Committee. The resident will be invited to attend the meetings of the Core Committee to evaluate and discuss their experiences, and should be encouraged to make a presentation on their project. The department head or delegate of each rotation are encouraged to complete a form in order to provide feedback to the resident.
- 5. The purpose of the elective activities is designed to meet the special interests of the resident and can involve additional time in any one of the core rotations, or other areas of expertise offered by the company. Other items to be listed under elective activities may include professional affairs and pharmaceutical association work.
- 6. List of general residencies:
 - The General Residency is not currently being offered by any companies.
- 7. A check list of requirements for the residents in order that the program may be successfully completed on time is:

General Residency Program Requirements

- a. At least six core rotations each of at least two weeks duration
- b. Major project
- c. Elective activities
- d. Two meetings of the Core Committee

VIII. INFORMATION FOR THE SPECIALTY RESIDENCY

The Specialty Residency is 12 months in duration. The program empowers the specialty resident to focus activities in one or two particular departments, providing a unique opportunity to develop specialty skills in chosen area(s) of interest. These skills should become highly marketable in the pharmaceutical industry.

See the website for current list of companies and specialty residencies offered.

The specialty resident participates in daily activities of the area(s) chosen in order to gain understanding of the operations of that department and achieve the necessary competencies of that position. Residents will choose projects offered by the supervisor, including a major project. Opportunities to attend seminars and conferences relating to both pharmacy and the area of specialty are pursued.

A check list of requirements for the residents in order that the program may be successfully completed on time is:

Specialty Residency Program Requirements

- a. Full daily active educational participation in the selected area of the residency e.g. market access, medical information, etc.
- b. A major project
- c. At least two meetings of the Core Committee

IX. INFORMATION FOR BOTH GENERAL AND SPECIALTY RESIDENCIES

- 1. **Conference:** The company supervisor may send the resident to a conference paid for by the company.
- 2. **External rotations:** Supervisors may wish to encourage their residents to take advantage of the following possible opportunities:
 - a. A visit to the operations of the company in a foreign country, usually the USA
 - b. Consider a rotation of 2-3 days at the Ontario Pharmacists Association's Drug Information and Research Centre, Contact phone 416-385-3472. For a one-month rotation, an honorarium is required.
 - c. Consider a one-month rotation at the Canadian Agency for Drugs and Technologies in Health (CADTH). Preference would be for a resident who would have completed a drug information rotation prior to coming to CADTH. Contact Sydney Payette at 613-226-4969 ext. 1319, email SydneyP@cadth.ca
- 3. **Major project:** The major project can be conducted within the company or with a combination of the company and the Faculty. The resident will write a proposal for the major project for presentation to the Core Committee, to be approved by the end of January. While the general supervision of the major project will be the responsibility of the Core Committee, individuals with required expertise from within the company, the Faculty or both may assist or direct the resident's project. The scope of the major project will depend on the expertise and resources available.

The final project report must be in a suitable format for presentation to the Core Committee (at a minimum) and, to appropriate departments within the company. The report should be reviewed by the company supervisor before presenting. If the report is confidential in nature, the Faculty Liaison (see Appendix VIII) should sign a confidentiality agreement before presentation of the report. Guidelines for the project and preparing the report are provided in Appendix II.

4. **Criteria for Completion of the Program:** In order to receive the certificate, the resident must complete all the work of the program and the major project within one year of commencing the program. The residency is a full-time 12-month duration program; the rotations and work related to the major project must be completed within this time. Under extenuating circumstances, the last month can be completed on a part-time basis over two months, with <u>prior</u> approval of the Core Committee and the Faculty Residency Coordinator. A resident must work at least 11 months in their placement to be eligible for a program certificate, even if their early departure is a result of being hired by the same company.

The company supervisor and/or the Faculty Liaison should inform the Residency Coordinator of the resident's successful completion of the program so that the certificate can be prepared. The certificate, attesting to successful completion of the program, will be signed by appropriate representatives of the company, such as the president and supervisor, and by the Faculty, usually the Dean and Faculty Liaison.

If the resident is not able to meet the requirement of completing all work of the program and the major project within one year of commencing the program, the resident may appeal in writing to an ad-hoc Appeals Committee, through the Residency Coordinator, providing reasons for seeking an extension. The Appeals Committee will consist of the Residency Coordinator or designee, one Faculty Liaison and one supervisor (these shall be different than the supervisor and liaison for the resident). The Appeals Committee can accept the appeal and state the date when the residency program must be completed, or reject the appeal. If the appeal is rejected, the appeal can be re-submitted by the resident to the overall Industrial Pharmacy Residency Program Committee, which usually meets in May, for a final decision.

X. ADMINISTRATIVE INFORMATION FOR BOTH RESIDENCIES

- 1. During the first week of the resident's program, the resident should be introduced by the supervisor to the people who are responsible for the program in each of the core areas. It is highly recommended that small projects be planned for the resident in each of the core areas. This will enable the resident to achieve a greater depth of understanding, appreciation and interest in the various areas. This should be a learning experience for the resident. The resident should not be filling a staff position or asked to perform relief work
- 2. In addition to the general objectives described in Sec. V, it is highly recommended that at the beginning of the residency, a set of learning objectives be established for the resident, in consultation with the supervisors. This will provide more structure to the residency and serve as the basis for providing evaluation and feedback regarding the resident's performance. Sample templates for setting the learning objectives and evaluation of resident's performance can be found in Appendix III.
- 3. The resident's registration fee (\$50) for the University of Toronto will be paid by the resident prior to starting the year. The resident may request the company to reimburse them for this fee. This fee will allow the resident to use the University of Toronto Library.
- 4. The company should endeavor to provide the resident with a permanent workstation in order to give them a space in which to prepare reports and to facilitate communication.
- 5. The company supervisor should increase the awareness of the resident and residency program within the company by means such as the company newsletter. It would also be beneficial for current resident(s) to meet with new resident(s) to help provide an increased understanding of the program.
- 6. The Core Committee oversees the residency at a particular company, and is composed of:

Company Supervisor - at the participating company Faculty Liaison (see <u>Appendix VIII</u>) – appointed by the Dean Resident

It is essential that the Core Committee meet at least twice during the residency in order to help in the direction of the program and the project. The first meeting should take place within the first month of the resident's program and other meetings should be tentatively set at the first meeting. It is the responsibility of the company supervisor to ensure that the first meeting will be held early in the program so that the resident has an early contact with the Liaison.

- 7. The primary role of the Faculty Liaison is to serve as an advocate for the resident, and to assure that the goals of the residency are being met. In this role, the Faculty Liaison should meet early in the residency with the resident and company supervisor to establish a program/schedule for the resident. This should be consistent with the purpose and structure of the residency program.
- 8. The Faculty Liaison should be involved in the design and evaluation of the major project. Should the project be in an area different from the expertise of the Faculty Liaison, it is the responsibility of the Faculty Liaison to seek to identify, in consultation with the Residency Coordinator, a member of the Faculty who could become involved with the project design and evaluation.
- 9. At a Core Committee meeting held in or prior to January, the resident shall outline the proposal for the major project including the proposed methodology and research design. At this meeting, the Core Committee will provide formative feedback and formally accept or reject the proposal. The resident will present updates on the status and progress of the project at each subsequent committee meeting. The Core Committee will provide ongoing support and feedback. At the final meeting, the resident shall present the project (see Appendix II for Guidelines). Although the written report may not be complete at this final meeting, the Core Committee shall formally accept or reject the major project as partial fulfillment of the requirements for the residency program, contingent upon receipt of the acceptable final project report. If the final meeting is positive and all other requirements have been met, the recommendation for awarding the certificate can be made.
- 10. Overall direction and guidance for the Industrial Pharmacy Residency Program will be provided by the Program Committee, with whom the ultimate responsibility for all aspects of the program rests. The Program Committee will meet at least annually (usually in May) to guide the Residency Program. It is composed of the following persons:
 - Dean of the Leslie Dan Faculty of Pharmacy, University of Toronto, or designate
 - Faculty Residency Coordinator
 - Faculty Liaison members appointed to each company
 - Representatives from each company, including a designated supervisor for each residency position
 - OPRA (Ontario Pharmacy Residents' Association) Industrial Pharmacy Representative Each resident enrolled in the current year is expected to attend as a guest.
- 11. Should issues or problems arise during the residency, the resident should, in the first instance, attempt to resolve these with the company supervisor. If this fails, the resident should then seek the advice and direction of the Faculty Liaison to resolve the problem. Should the problem not be resolved in this manner, the resident should then contact the Residency Coordinator.

XI. ADDITIONAL INFORMATION FOR BOTH RESIDENCIES

- 1. Each company will provide a description of their specific Industrial Pharmacy Residency placement(s) and the abilities and characteristics of the resident expected by the supervisor. This information will be no more than two pages long, and should be submitted to the Faculty by August 1, so that this information is available to applicants, on the website.
- 2. Applicants are encouraged to apply to those companies which have interests similar to their own and to which they would like their applications sent, see Appendix VII.
- 3. Information on housing in Toronto can be found at: https://www.studentlife.utoronto.ca/hs/about-us
- 4. Prospective residents are encouraged to talk to current residents about the program.

The following are residents in 2019-2020:

Mathew Chun-Yun Luen Amgen Canada 6775 Financial Drive, Suite 100 Mississauga, ON L5N O4A

Flora Gao Astellas Pharma Canada 675 Cochrane Dr. Suite 500, West Tower Markham, ON L3R 0B8

Alhusein Hussin Bayer Canada 2920 Matheson Blvd E, Mississauga, ON L4W 5R6

Parinaz Shahrezaei *Eli Lilly Canada Inc*. 3650 Danforth Avenue Toronto, ON M1N 2E8

Jekaterina Davydova *Hoffmann-La Roche Limited* 7070 Mississauga Road Mississauga, ON L5N 5M8 Katarina Vuckovic *Amgen Canada*6775 Financial Drive, Suite 100
Mississauga, ON L5N O4A

Salimah Champsi **Bayer Canada** 2920 Matheson Blvd E, Mississauga, ON L4W 5R6

Amanda Lee *Biogen Idec Canada Inc.*Suite 1100, Sussex Centre
90 Burnhamthorpe Road West
Mississauga, ON L5B 3C3

Shannon Chowdhury *Hoffmann-La Roche Limited*7070 Mississauga Road
Mississauga, ON L5N 5M8

Kiana Gozda *Hoffmann-La Roche Limited* 7070 Mississauga Road Mississauga, ON L5N 5M8 Manny Khaira *Hoffmann-La Roche Limited* 7070 Mississauga Road Mississauga, ON L5N 5M8

Munaza Saleem Hoffmann-La Roche Limited 7070 Mississauga Road Mississauga, ON L5N 5M8

Timothy Tin Yue Yu **Purdue Pharma** 575 Granite Court Pickering, ON L1W 3W8

Eugene Choi *Sanofi Genzyme* 800 West – 2700 Matheson Blvd E Mississauga, ON L4W 4V9

Hui En Sally Chen Sanofi Pasteur 1755 Steeles Avenue West Toronto, ON M2R 3T4

Vincent Nguyen Sanofi Pasteur 1755 Steeles Avenue West Toronto, ON M2R 3T4 Katie Lee *Hoffmann-La Roche Limited* 7070 Mississauga Road Mississauga, ON L5N 5M8

Jonathan Nhan *Novo Nordisk* 101-2476 Argentia Raod Mississauga, ON L5N 6M1

Christy Cheung Sanofi Genzyme 800 West – 2700 Matheson Blvd E Mississauga, ON L4W 4V9

Carly Sterling Sanofi Genzyme 800 West – 2700 Matheson Blvd E Mississauga, ON L4W 4V9

Nausha Hooda *Sanofi Pasteur* 1755 Steeles Avenue West Toronto, ON M2R 3T4

Anastasia Pimenova *Sanofi Pasteur* 1755 Steeles Avenue West Toronto, ON M2R 3T4

XII. FINANCIAL SUPPORT

The resident will be an employee of the company, on a special project basis. The same stipend will apply to each and every program. It will be established yearly. For 2019-2020 the stipend for the specialty residency is \$51,510. For 2020-2021 the stipend for the specialty residency will be \$52,540. Note that all programs currently are designated as 'specialty'.) It should be noted that while the stipend is uniform at all participating companies, the benefits are not uniform. The applicant should seek information regarding individual benefits from those companies to which the applicant is applying. The benefits may include for example: vacation time, health benefits and attendance at conferences.

APPENDIX I

COMPANY SUPERVISOR CONTACT INFORMATION

Martin Cho, Supervisor Director, Market Access & Government Relations Allergan Inc. 85 Enterprise Blvd., Suite 500 Markham, ON L6G 0B5 E-mail: Cho_Martin@Allergan.com	Maureen Bot, BScPhm, Supervisor Senior Manager Medical Information Amgen Canada 6775 Financial Drive, Suite 100 Mississauga, ON L5N O4A Tel: 905-285-3048 Email: mbot@amgen.com Faculty Liaison: Paul Grootendorst
Mirjana Chionglo, PharmD, Supervisor Senior Product Manager Amgen Canada 6775 Financial Drive, Suite 100 Mississauga, ON L5N O4A Tel: 905-285-3048 Email: mirjanac@amgen.com Faculty Liaison: Paul Grootendorst	Naivin Sayani, Supervisor Associate Director, Medical Operations, Medical Affairs Astellas Pharma Canada 675 Cochrane Dr. Suite 500, West Tower Markham, ON L3R 0B8 Tel: 905-946-5618 E-mail: naivin.sayani@astellas.com Faculty Liaison: Certina Ho
Jason Lee, Supervisor Director Market Access Bayer Inc. 2920 Matheson Blvd E Mississauga, ON L4W 5J4 E-mail: jason.lee2@bayer.com Faculty Liaison: TBA	Mohammed Mahdi, Supervisor Senior Manager, Medical Scientific Advisor-Hematology Bayer Inc. 2920 Matheson Blvd E Mississauga, ON L4W 5J4 Tel: 905-282-5532 E-mail: mohammed.mahdi@bayer.com Faculty Liaison: TBA
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Joanna Rizos, Supervisor Medical Affairs Manager Eli Lilly Canada Inc. 3650 Danforth Avenue Toronto, ON M1N 2E8 Tel: 416-693-3849 E-mail: rizos_joanna@lilly.com Faculty Liaison: Marie Rocchi	Haron Mark Jeddi, Supervisor Director, Pricing, Reimbursement and Patient Access Eli Lilly Canada Inc. 3650 Danforth Avenue Toronto, ON M1N 2E8 Tel: 416-699-7443 E-mail: jeddi_haron_mark@lilly.com Faculty Liaison: Paul Grootendorst

Wilson Cheng Marni Freeman Medical Affairs Medical Director GlaxoSmithKline Inc. GlaxoSmithKline Inc. 7333 Mississauga Road North 7333 Mississauga Road North Mississauga, ON L5N 6L4 Mississauga, ON L5N 6L4 E-mail: wilson.x.cheng@gsk.com E-mail: Marni.A.Freeman@gsk.com Chi-Sing Nip, Pharm.D., M.B.A., Supervisor **Donna Janzen** Director, Global Labeling & Established Products Director, Medical Excellence, Medical Affairs Hoffmann-La Roche Limited Hoffmann-La Roche Limited 7070 Mississauga Road Product Development Regulatory (PDR) Mississauga, ON L5N 5M8 7070 Mississauga Road Tel: 905-542-5676 Mississauga, ON L5N 5M8 Tel: 905-542-5709 E-mail: donna.janzen@roche.com E-mail: chi-sing.nip@roche.com Faculty Liaison: David Dubins/Micheline Piquette Faculty Liaison: David Dubins/Micheline Piquette Jennifer Rilstone Lisa Cesario Regulatory Documentation Team Leader Medical Affairs Hoffmann-La Roche Limited Hoffmann-La Roche Limited 7070 Mississauga Road 7070 Mississauga Road Mississauga, ON L5N 5M8 Mississauga, ON L5N 5M8 E-mail: jennifer.rilstone@roche.com E-mail: <u>lisa.cesario@roche.com</u> Faculty Liaison: David Dubins/Micheline Piquette Faculty Liaison: David Dubins/Micheline Piquette Rishma Abdulhusein **Jasmine Gil** Director, Medical Strategy Regulatory Operations Team Leader Hoffmann-La Roche Limited Hoffmann-La Roche Limited 7070 Mississauga Road 7070 Mississauga Road Mississauga, ON L5N 5M8 Mississauga, ON L5N 5M8 E-mail: rishma.abdulhusein@roche.com E-mail: jasmine.gil@roche.com Faculty Liaison: David Dubins/Micheline Piquette Faculty Liaison: David Dubins/Micheline Piquette Vicky Chan, Supervisor VP-Clinical Development, Medical & Regulatory Affairs Novo Nordisk 101-2476 Argentia Raod Mississauga, ON L5N 6M1 Tel: 905 206 2283 E-mail: vcch@novonordisk.com Faculty Liaison: Certina Ho Abdullah Aboukarr, BSc, PharmD, RPh Adrianna Ziff, M.Sc.Pharm., R.Ph., Supervisor Director, Drug Safety/Pharmacovigilance & Product Pharmacovigilance & Drug Information Officer Information, Medical Affairs Medical Affairs Purdue Pharma Purdue Pharma 575 Granite Court 575 Granite Court Pickering, ON L1W 3W8 Pickering, ON L1W 3W8 Tel: 905-421-3334 Tel: 905-421-3334 E-mail: Abdullah.Aboukarr@purdue.ca E-mail: Adriana.Ziff@purdue.ca Faculty Liaison: Rob Bonin

Yohan D'Souza Amit Suri, MSc, Supervisor Medical Director, Head of Multiple Sclerosis Medical Director, Rare Disease Sanofi Genzyme Sanofi Genzyme 800 West – 2700 Matheson Blvd E 800 West – 2700 Matheson Blvd E Mississauga, ON L4W 4V9 Mississauga, ON L4W 4V9 Tel: 905-625-0011 E-mail: Yohan.dsouza@sanofi.com E-mail: Amit.Suri@sanofi.com Faculty Liaison: Ping Lee Faculty Liaison: Ping Lee Austin Hung, PharmD, Supervisor Dion Neame, MD, BCh, BSc, FRCPC, FAAP, Deputy Director, Regional Medical Strategy **Supervisor** Sanofi Pasteur Country Medical Chair and Head of Medical Pasteur 1755 Steeles Avenue West Toronto, ON M2R 3T4 Sanofi Tel: 416-667-2069 1755 Steeles Avenue West E-mail: Austin.Hung@sanofi.com Toronto, ON M2R 3T4 Faculty Liaison: Vinita Arora/Linda Dresser Tel: 416-667-2884 E-mail: Dion.Neame@sanofi.com Faculty Liaison: Vinita Arora/Linda Dresser Dave McEachran, MSc, Supervisor Head of Compliance Sanofi 1755 Steeles Avenue West Toronto, ON M2R 3T4 Tel: 416-667-2796 E-mail: Dave.McEachran@sanofi.com Faculty Liaison: Vinita Arora/Linda Dresser

APPENDIX II

PROGRAM GUIDELINES FOR MAJOR PROJECT

1. Philosophy:

To conform with the Industrial Pharmacy Residency Program requirements, a major project must be undertaken and successfully completed as partial fulfillment of the residency program. This will require the resident to develop and use effective project management or research skills while gaining practical problem-solving experience. The resident will be expected to apply a systematic approach to the investigation, analysis and response to an identified issue or question of relevance to the Industry.

While the project need not be an original idea or issue, it should not solely be a literature search. However, a 'systematic review' using a robust methodology¹, could be considered by the Core Committee for approval.

2. Expectations:

a. Of the Company

While the project may represent a collaborative venture between various professionals, the company must identify a supervisor who shall take full responsibility for the resident's work.

Within two months from the starting date of a resident's program, the company supervisor shall provide the resident with a reasonable list of potential projects, (e.g. 3-6) from which a selection shall be made not later than January 31. The resident may help generate the list.

b. Of the Resident

i) The nature of the project

Although many widely differing projects could meet the requirements, several principles shall be applied. First, the project shall be acceptable to the Core Committee. Second, while it may serve the needs of the company, the project shall be worthwhile to the degree that it permits the resident to gain practical problem-solving experience through project management or research. Finally, it is important that the project is feasible and can realistically be completed in the time frame available.

ii) Selecting a project

The company supervisor, as indicated above, shall generate a list of project ideas from which the resident can make a choice. The resident may also have independent views on a particular project. The overriding principle should be that the resident and the company supervisor agree on a worthwhile and feasible project. Where appropriate, the major project should be planned

¹ Resources to guide Systematic Reviews: PRISMA http://www.prisma-statement.org/; AMSTAR: http://amstar.ca/; CADTH https://cadth.ca/critical-appraisal-clinical-practice-guidelines

with a view to formal publication.

iii) The time allotted for the project

A total of three months shall be devoted to the project. To facilitate progress on project components, this time could be spread across the year rather than as a single block.

iv) Reporting on the project

The completed project shall be presented to the Core Committee. A final written report shall also be compiled, organized like a publication, containing, for example, the following headings. Note: for non-research based projects, some alternate headings are shown in [brackets]:

- Title page
- Abstract (up to 250 words)
- Acknowledgments
- Introduction/background
- Objective(s) [description]
- Methodology [action]
- Results [evaluation] including tables, figures
- Discussion [implications], including recommendations; relationship to current literature; and suggestions for further research [further work]
- Conclusions
- References
- Appendices

3. Guidelines for Residents' Presentation at Annual IPRP Meeting

- a) Each resident will be allotted 6 minutes, and may have up to 5 slides to support their verbal presentation.
- b) The resident will need to email a copy of any slide material to Chair three business days prior to the meeting, to enable loading onto meeting computer and efficient transition between presenters. (Note: slides will be kept confidential and not shared outside of the Residency Coordinator's office and administrative assistant for the office.)
- c) Presentations will be high-level/brief to keep within the time window. The resident's major project may be aligned with traditional research or project management, therefore alternative headings are acceptable, such as the following:

Include title, followed by:

- i) for research-based projects: background, objectives, methods, results, discussion, conclusions
- ii) for non-research-based projects: background, description, action, evaluation, implications, conclusions

- d) Some information on the major project may be confidential/proprietary; resident will not disclose such information in this meeting setting. Resident should arrange for their company supervisor to review presentation slides prior to sending.
- e) The resident is encouraged to also include a verbal comment and/or a slide about any key/unique learning opportunities, reflections they wish to share.
- f) The resident should aim to complete their presentation in 5 minutes, followed by a 1-minute question/comment period from the audience.

APPENDIX III

SAMPLE TEMPLATES

For Learning Objective Setting & Evaluations of Industrial Pharmacy Residents

The attached templates were kindly provided by Lisa Li, Pharmacy Resident in Drug Information at Astellas Pharma for 2013-2014, who designed these forms for Medical Information Specialty during her residency as Astellas. Interested companies and residents should be able to adopt these forms either as-is or in modified form to suit their individual needs. Lisa Li has also provided the following synopsis regarding these template forms:

There are 4 forms attached – Learning Objectives, Presentation Evaluation, Medical Information Residency Evaluation and Major Project Residency Evaluation.

Setting the **Learning Objectives** for the residency is to further enhance the learning of the residency, beyond those objectives set for the specialty residency itself. Examples can include exposure to different departments within the company, participating in a company sponsored conference, etc. This is to be set at the beginning of the residency, and with the guidance of the Director so there is ample opportunity for these types of activities throughout the year.

The **Presentation Evaluation** is a multi-purpose form that allows the resident to gain formal feedback after delivering any presentation.

The Medical Information **Residency Evaluation** is to evaluate the knowledge and competencies of the resident within the specialty residency itself (in our case, the specialty is in Medical Information) and also assessing professional behaviors. We thought it would be best to assess this at midpoint and end of residency (to assess progress over the year), with an opportunity for a self-evaluation and supervisor evaluation.

The Major Project Evaluation is to evaluate different aspects of project management with the major project. This includes teamwork, project planning, communication skills, attitudes and behaviors. We also thought it would be best to assess this at midpoint and end of residency, with an opportunity for a self-evaluation and supervisor evaluation.

Personal Learning Objectives

Resident Na	ame:
Supervisor	
Name: Dire	ctor
Name:	

The following objectives for this rotation are the result of negotiations between the resident, the supervisor and the Director of Medical Affairs, and include:

- objectives that educate the resident about different teams within Medical Affairs
- objectives that expose the resident to different areas of the company's departments

Do not include Medical Information Residency Program Objectives listed on the Residency Program Guide.

The learning objectives should be reviewed at the midpoint and final assessment.

LEARNING OBJECTIVE	RATIONALE FOR LEARNING OBJECTIVE

Sample Template

Presentation Evaluation

Resident's	
Name: Date:	
Presentation	
Title:	

Performance level:

1 = did not meet expected level of performance 2 = met expected level of performance 3 = exceeded expected level of performance N/A = not applicable

Evaluation Criteria	Performance Level	Comments
Presentation Content:		
Presents good background information and rationale		
Demonstrates critical assessment of the topic		
Provides appropriate recommendations and/or conclusions		
Able to comment on the practical application of the presentation to the practice site		
Presentation Skills:		
Presentation organization		
Presentation skills (eye contact, pace, clarity)		
Response to questions		

Overall Comments (including strengths and areas for improvement):

Sample Template

Medical Information Residency Evaluation

Resident's Name:	Supervisor:
Date:	
Mid-point Evaluationor Final Evaluation _	<u></u>
Supervisor Evaluationor Self-Evaluation _	

Performance level:

1 = did not meet expected level of performance 2 = met expected level of performance 3 = exceeded expected level of performance N/A = not applicable

Evaluation Criteria	Performance Level	Comments
Knowledge and Competencies:		
Provide accurate, fair-balanced, and current medical and technical information regarding Company products to healthcare professionals, patients and consumers.		
Respond to inquiries in both verbal and written formats and tailor responses to the target audience		
Develop and/or update standard response medical letters		
Perform and evaluate literature searches to stay current on the latest scientific information and disseminate Literature Updates to Therapeutic Area team members		
Apply documentation skills by utilizing the departments' inquiry management database		

Formulate adverse event and product complaint reports from medical inquiries				
Review promotional materials and provide input on marketing programs and advertisements to ensure compliance with laws and regulations				
Professional Behavioural Asses	ssment:			
Demonstrates ability to complete assigned tasks in a timely fashion				
Demonstrates self-directed learning and independence of action, and seeks consultation where appropriate				
Overall Comments (including Date of Review: Resident's Signature	y strengths an	d areas for improver	ment):	
Resident 5 Oignature				
Supervisor's Signature				
Director's Signature (Final Evaluation Only)				

Sample Template

Major Project Evaluation

Resident Name:	Supervisor
Name: Date:	
Self-Evaluation	Project Supervisor Evaluation
Mid-point Evaluation_	or Final Evaluation

Performance level:

1 = did not meet expected level of performance 2 = met expected level of performance 3 = exceeded expected level of performance N/A = not applicable

Evaluation Criteria	Performance Level	Comments
Knowledge and Skills:		
Project Planning		
Adherence to schedule and work productivity		
Ability to work in a team		
Ability to anticipate and analyze problems		
Quality of work		
Decision making skills		
Oral communication skills		
Written communication skills		
Contribution and value added to Medical Affairs department		
Attitudes:		
Ability to evaluate and respond to constructive feedback in a positive manner		
Demonstrates self-directed and independence of action, and seeks consultation where appropriate		
Dependability and accountability		

Overall Comments:

APPENDIX IV

DEFINITIONS

Medical/Scientific Affairs

Bioavailability:

measurements of the rate and extent of drug absorption.

Clinical Research:

the design and monitoring of scientifically valid and ethical studies in humans for investigational drugs, new drugs and new indications for marketed drugs.

Medical/Drug Information:

responds to all medical inquiries from sales representatives, health-care professionals, consumers and departments within the company. Reviews medical literature. Ensures compliance of all medical marketing materials.

Post Marketing Surveillance:

monitoring of drug use, adverse reactions and drug effectiveness.

Regulatory Affairs:

gathering, interpreting, summarizing and formatting information to submit to the government for approval for the sale of a drug. Ensuring that all departments of the company operate according to the Food and Drugs Act and regulatory guidelines.

Statistical Analysis:

statistical analysis of data from clinical research and other studies.

Product Development and Formulation:

the processes involved in the creation of dosage forms and their development for commercial use.

Marketing

Market Access:

Seeking reimbursement through public/private payor.

Market Research:

collecting information on prescribing habits and prescriptions to assist in designing better marketing strategies.

Product Management:

strategic business responsibilities for product(s) from manufacturing through to pricing and advertising with the ultimate goal of making a profit.

Promotion and Advertising:

a product is promoted and advertised to the health science community (e.g. through sales representatives and professional journal advertising).

Sales

Consumer Sales:

promoting non-prescription products through displays and other incentives.

Pharmaceutical Sales:

sales representatives call on doctors and pharmacists to familiarize and/or introduce them to the company's products.

Sales Training:

the program(s) necessary to prepare a sales representative to call on doctors and pharmacists in various specialties for the promotion of the company's products and services.

Production

Manufacturing:

the combination and manipulation of raw materials in large quantities to produce the final dosage form.

Packaging:

the assembly of the drug into its container and labeling for shipment.

Quality Control/Quality Assurance

Quality Assurance:

monitoring to ensure that standard operating procedures are being carried out according to internal procedures and government regulations.

Quality Control:

testing, from the receipt of raw materials to the shipping of the final product, to ensure that standard specifications are met.

Managed Care:

the administration of health care resources for the efficient and effective treatment of disease and the promotion of health to enhance the quality of life.

Pharmacoeconomics:

the description and analysis of the costs (i.e. resources consumed) and consequences of pharmaceutical products and services.

APPENDIX V

(moved under Appendix VII)

APPENDIX VI

The Award

The Program Committee of the Industrial Pharmacy residency Program consisting of the Leslie Dan Faculty of Pharmacy in cooperation with the participating companies has sponsored an Award consisting of a plaque and \$1000.00 to acknowledge one resident who has completed a major project of high quality and who has demonstrated leadership qualities and undertaken new initiatives during his or her residency. Normally the award is given to one resident, however under certain circumstances the award may be split into two awards of equal value. Residents applying for the award shall provide a copy of their major project and documented evidence indicating leadership qualities and new initiatives during their residency, to the Residency Coordinator, Industrial Pharmacy Residence Program of the Leslie Dan Faculty of Pharmacy by October 31 of the year they complete the residency. Only applicants who have completed all the requirements of the program within one year of beginning are eligible to apply for the award unless there are extenuating circumstances. The selection process is arranged by the Residency Coordinator, who will invite three faculty members (none of whom are liaison members at the companies where submissions have arisen from) to serve on the review group to assess each submission. Assessment criteria, guided by a scoring rubric, will consider the major project report and documented evidence of leadership qualities and initiatives.

APPENDIX VII

APPLICATION FORM

See Section III for Application Procedure; access to the online form is provided via the IPRP website.

Note to Prospective Residents: Since your application will be your communication with the companies of interest to you, it is essential that it be completed in a knowledgeable, concise and clear manner. This application is usually responsible for forming a first impression with the company's supervisor and consequently, is important in the selection of candidates for the residency. You should find out about the companies of your choice as suggested in Section III (APPLICATION PROCEDURE), item 1. Annual reports or similar information should be available on company websites. You should have sufficient knowledge about the company so that you may make a suitable selection and are able to answer questions about the company during the interview.

APPENDIX VIII FACULTY LIAISON

Guidelines for the Role of the Faculty Liaison

(Approved at May 2, 2018 Meeting of Industrial Pharmacy Residency Program, updated July 2019)

Introduction:

The Industrial Pharmacy Residency Program is a one-year program, administered by the Leslie Dan Faculty of Pharmacy, University of Toronto in cooperation with participating pharmaceutical companies. While it is understood that the host company is solely responsible for the residency program, input into the training experience is established through the residency Core Committee, which includes a Faculty (Academic) Liaison, appointed by the Dean of the Leslie Dan Faculty of Pharmacy, usually for a 3-year term, renewable.

The Core Committee shall be in place to provide general oversight and guidance to the design and operation of the residency at the particular company, and is composed of:

- Company Supervisor of the Resident
- Faculty (Academic) Liaison a Leslie Dan Faculty of Pharmacy Faculty member appointed by the Dean
- Company representative external to the primary department where the resident is assigned; this could include a senior representative to whom the department reports
- The resident(s)
- The Committee may also have regular or ad-hoc input from preceptor(s) of the pharmacy resident

When more than one residency position exists, the company can decide if more than one Core Committee may be warranted. The Faculty may appoint more than one Faculty Liaison to a company.

Responsibilities of the Faculty Liaison:

- 1. To serve as an academic advocate for the resident.
- 2. To regularly attend the Core Committee meetings, in person or by teleconference. Meeting frequency will be program dependent, and should occur at least twice per year.
- 3. To advise the resident in the development of their project to ensure its quality and feasibility.
- 4. To propose potential project collaboration and/or supports, where possible. For example, the Faculty Liaison may facilitate referral of the resident to the expertise of colleagues at the Faculty if necessary.
- 5. To review the project proposal, other reports and the final project report.
- 6. To inform (in conjunction with the company supervisor), upon the resident's successful completion of the program requirements, the Faculty Residency Coordinator. This will enable preparation of the certificate, coordinated by the Faculty.
- 7. Through participation on the Core Committee, offer input with respect to suggestions for quality improvement of the residency program.
- 8. To provide the Core Committee with updates from the Faculty that relate directly to the residency program. (Note: the Faculty Residency Coordinator will also provide Faculty updates to the companies as needed during the year.)
- 9. To attend the annual Industrial Pharmacy Residency Program meeting, held at the Faculty.

It is expected that the host company will compensate the Faculty Liaison for travel, accommodation and meal expenses incurred for Core Committee meeting attendance.