

	2017 List of Consultants (see Disclaimer)				
Company Name /	Contact Information	Summary of Services (see Notes)			
Address	Contact Information	Product Areas:	Services:	Countries:	
AAPS-Academy of Applied Pharmaceutical Sciences 200 Consumers Road, Suite 200 Toronto, Ontario M2J4R4 Canada	Tel: 416-502-2277 Fax: 416-502-2278 <u>laleh@aaps.ca</u> <u>http://www.aaps.ca</u>	Pharmaceuticals Biologics Veterinary Drugs Medical Devices Cosmetics Over-the-counter Products Natural Health Products	• Whatever you're regulatory, quality, laboratory or clinical research project is, AAPS can serve as your strong partner. We have access to and work with some of the brightest minds in Quality, Compliance, Laboratory, Safety, Regulatory, R&D, and Operations bringing together decades of experience. We work side-by-side with you to create solutions that help you achieve what you want to achieve.	Canada United States Europe Asia Africa Australia Latin America	
Access-Pharma Group, CRA School and ACR SMO/CRO 6767 Cote-des-neiges, Unit 601-1, Montreal, QC H3S 2T6 Canada	Tel: 514 961-9351 Fax: 514 257-0444 <u>info@cra-school.com</u> <u>http://www.cra-school.com</u>		Canadian Clinical Research Certification and Job Insertion Program with internship and coop placement in the affiliated SMO/CRO ACR, providing Unit in demand services worldwide: qualified CRC, PI recruitment and training, and Sponsors' SOP implementation.		
ACERNA Inc. 270 Riverlands Avenue, Markham, Ontario L6B 0W2 Canada	Paul J. Larocque, President Tel: 905-472-5747 paul.larocque@acerna.ca www.Acerna.ca	Pharmaceuticals Biologics Medical Devices Over-the-counter Products	<ul> <li>Good Manufacturing Practices, especially for sterile, aseptic, and biological processes</li> <li>Compliance resolution, including Health Canada and FDA Warning Letters</li> <li>Medical Device Quality Systems</li> <li>Regulatory Affairs</li> </ul>	Canada United States Europe	



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Adiantum Consultant-e Inc. Boucherville Québec	Julie Naud Tel: 450-641-2696 Fax: 450-655-0204 <u>j.naud@adiantumconsultant- e.com</u> <u>www.adiantumconsultant- e.com</u>	Food Cosmetics OTC drugs Natural Health Products Dietary supplements	<ul> <li>Natural Health Product (NPN)</li> <li>Over-the-counter Drug (DIN)</li> <li>Cosmetic</li> <li>Site licensing</li> <li>SOPs</li> <li>Supplement/Nutrition Facts Table</li> <li>Product label text revision</li> </ul>	Canada United States
Amosey Inc. 39-173 Advance Boulevard Brampton, ON L6T 4Z7 Canada	Jai Velusamy Tel: 416-822-5625 jai@amoseyinc.com www.amoseyinc.com	Pharmaceuticals Biologics Veterinary Drugs Medical Devices Cosmetics Over-the-counter Products Natural Health Products Food	<ul> <li>A to Z of Pharmaceutical Industry</li> <li>Establishment/Site Licensing,</li> <li>Regulatory Submissions, eCTD</li> <li>Compliance, GMP/ISO,Auditing</li> <li>QA, Validation, Clinical Research,</li> <li>Pharmacovigilance, Formulary</li> <li>Importation, Distribution</li> <li>Certificate of Free Sale/ITC</li> <li>Translation &gt; 30 languages</li> </ul>	Canada United States Europe Asia India Australia
AxSource Consulting Inc. 336 Bronte Street South Suite 225 Milton, ON L9T 7W6 Canada	Ms. Navneet Sekhon, President Tel: 905-854-6059 Cell: 416-452-0100 <u>nav.sekhon@axsource.ca</u> <u>www.axsource.ca</u>	Drugs/Pharmaceuticals Biologics Veterinary Drugs Medical Devices Cosmetics Over-the-counter Products Natural Health Products Medical Marajuana	We provide complete support in pre- market product & facility authorizations, GMP/GLP/GCP/GDP compliance systems, post-market surveillance activities, and regulatory agency inspection readiness (e.g. FDA, Health Canada, MHRA etc.).	Canada United States Europe Asia Australia



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Bionatus Pharmacognosique/Bionat us Laboratorio Botanico LTDA 12600, 56e Avenue Montreal, Quebec H1E 2M6 Canada	Tel: 5148812510 <u>nzi@usp.br</u>		Natural Products 1. Health Canada - Site Licensing - Product Licence for Natural Health Products 2. ANVISA – Brazil - Registration and Authorization for companies - Registration and authorization for: Phytomedecines, Foods, Nutraceuticals Active Pharmaceutical Ingredients 3. Product development.		
BOYER@RegulatorySolns 28 Brady Avenue Ottawa, Ontario K2K 2R2 Canada	Mr. Don Boyer Tel: 613-592-6068 <u>don.boyer@boyerregulatorysol</u> <u>ns.com</u>	Medical Devices, Natural Health Products	• BOYER@RegulatorySolns provides expert regulatory and strategic advice for Medical Devices, NHPs & Pharma to the health products industry based on 30+ years of experience with Health Canada.	Canada United States Europe Australia	
Canadex Laboratories Inc. 725 Place Fortier #707 Montreal, Quebec H4L 5B9	Mr. Fayez Chehab Tel: 514-978-4466 Fax: 514-747-7550 <u>fayez@canadexlabs.com</u> <u>www.canadexlabs.com</u>	Pharmaceuticals Veterinary Drugs Medical Devices Cosmetics Over-the-counter Products Natural Health Products	<ul> <li>Health Canada drug submissions: (NDS) (SNDS) (ANDS) (NC) (DIN)</li> <li>Health Canada Natural Health products submissions: (NPN)</li> <li>Quality Control &amp; Quality assurance</li> <li>GMP Compliance &amp; Product registration</li> </ul>	Canada United States Europe Gulf Arabic States (GCC countries)	



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Certus PV Services 2 Robert Speck Parkway, Suite 766 Mississauga, ON L4Z 1H8	Rita Cassola Tel: 905-306-3448 <u>contact@certuspv.com</u> <u>www.certuspv.com</u>	Pharmaceuticals Biologics Radiopharmaceuticals Over-the-counter Products Natural Health Products Cosmetics Veterinary Drugs	Certus PV provides expert pre- approval and post-market pharmacovigilance as well as medical information services	Canada United States
Consultations Nathalie Lebel Inc. 1768 chemin St-Charles, Local 101 Terrebonne, Quebec J6W 0B7	Nathalie Lebel Tel: 450-416-0922 Fax: 450-416-4922 <u>nathalie.lebel@lebelpharma.com</u> <u>www.lebelpharma.com</u>	Pharmaceuticals Biologics Veterinary Drugs Medical Devices Cosmetics Over-the-counter Products Natural Health Products Marihuana for Medical Purposes Pharmacovigilance	<ul> <li>Regulatory affairs for cosmetics, OTC drugs, NHPs, medical devices, and food</li> <li>DIN, NPN applications, medical device licenses</li> <li>Liaison – Health Canada</li> <li>GMP training and inspections, SOP writing, QA/QC</li> <li>English or French package copy review, translations</li> <li>Environmental compliances</li> <li>Certificates of Free Sale (ITCs)</li> </ul>	Canada
Consultpharm Inc. 3230 Blv. Cure Labelle Suite 210 Laval, QC H7P 4W6	Mr. Magued Wasfy Tel: 514 920 0001 Fax: 514 920 0066 <u>mwasfy@consultpharm.com</u>	Pharmaceuticals Natural Health Products Medical Devices Cosmetics Over-the-Counter	<ul> <li>Regulatory Affairs</li> <li>Quality Assurance</li> <li>Pharmacovigilance Consultation</li> <li>Express Site Inspection</li> </ul>	Canada



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CRM Pharma Consulting Inc. 5877 Leeside Cres Mississauga, Ontario L5M 5L6 Canada	Tel: 647-205-9706 Fax: 905-593-9706 <u>mahdis.dorkalam@crmpharmaconsulting.com</u> <u>http://mahdis.dorkalam@crmpharmaconsulting.com</u>	Pharmaceuticals, Biologics, Medical Devices, Cosmetics, Over- the-counter Products, Natural Health Products	<ul> <li>20 years of experience in pharmaceuticals, biologics, NHP across numerous therapeutic areas.</li> <li>Project management</li> <li>Preparation and submission of clinical and CMC applications</li> <li>Dossier compilation and management</li> <li>DIN, NPN, Medical Device Applications</li> <li>Product Monographs and labelling.</li> </ul>	Canada	
Dell Tech Laboratories Ltd. 100 Collip Circle Suite 220 London, Ontario N6G 4X8 Canada	Teri Dickinson Jenner Tel: 519-858-5068 Fax: 519-858-5026 <u>tjenner@delltech.com</u> <u>www.delltech.com</u>	Over-the-counter Products Natural Health Products Veterinary Drugs Medical Devices Cosmetics Pest Control Products Consumer Chemicals and Containers	<ul> <li>Over 35 years experience in regulatory and compliance consulting</li> <li>Health Canada Regulatory classifications/strategies/submissions</li> <li>DIN/DEL/NPN/Site Licences</li> <li>Disinfectants/OTC/Cosmetics</li> <li>Nutritional Facts Table</li> </ul>	Canada	
DSA Consultants 1660 North Service Road East, Unit 107 Oakville, Ontario L6H 7G3 Canada	Tel: 905-827-0057 ext. 229 <u>info@dsaconsultants.com</u> <u>http://www.dsaconsultants.com</u>	Pharmaceuticals Biologics Veterinary Drugs Medical Devices Cosmetics Over-the-counter Products Natural Health Products	<ul> <li>Regulatory and Quality consulting services.</li> </ul>	Canada	



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Eric Leblanc Consultant Inc. 25 Bourdon Mercier, Québec, J6R 2R9 Canada	Eric Leblanc, RAC Tel:514-929-4891 <u>leblanceri@gmail.com</u>	Pharmaceuticals Biologics	<ul> <li>CMC regulatory affairs compliance</li> <li>IND and CTA in eCTD format</li> <li>Technical writing</li> <li>Technology transfer</li> <li>Analytical procedure development and validation</li> <li>Quality assurance</li> <li>GMP compliance audit</li> </ul>	Canada United States Europe		
Eurofins Experchem 1111 Flint Road Etobicoke, Ontario M8V 0B2 Canada	Tel: 416 433 4671 Fax: 416 665 9251 <u>CA01_GeneralInquiries@eurofins</u> .com <u>http://www.eurofins.ca</u>		• Eurofins is a global analytical testing and regulatory consulting entity. The company has over 200 locations in 40 countries with over 24,000 professionals to service your needs. Contact us for help with pharmaceuticals, cosmetics, natural health products, cannabis, medical devices and any other new consumer product to market.			
Focal Point Research Inc. 181 Lakeshore Rd. E. Mississauga, ON L5G 1G2	Jenn Porter Tel: 905-271-2709 ext. 229 Fax: 905-271-4540 jenniferp@focalpointresearch.net www.focalpointresearch.net	Medical Devices Cosmetics Over-the-counter Products Natural Health Products	<ul> <li>Regulatory Affairs</li> <li>Quality Assurance</li> <li>Product Labelling</li> <li>Ingredient Compliance</li> <li>Advertising Claim Support</li> <li>Cosmetic &amp; Drug Science</li> </ul>	Canada United States		



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GMD PharmaSolutions 1215B North Service Road W. Oakville, ON L6M 2W2	Mona Salesse Tel: 905-827-1300 ext. 1158 <u>msalesse@gmdpharma.ca</u> <u>www.gmdpharma.ca</u>	Pharmaceuticals Biologics Veterinary Drugs Medical Devices Over-the-counter Products Natural Health Products Controlled Substances	<ul> <li>Regulatory Affairs</li> <li>Quality Assurance</li> <li>Pharmacovigilance</li> <li>Warehouse services</li> <li>Importation</li> <li>Distribution</li> <li>Patient Programs</li> <li>Specialty Care Pharmacy</li> <li>Clinical Services</li> </ul>	Canada United States	
Innovia-Biopharma Inc. 141 rue ovila Rosemere, QC J7A4L2 CANADA	Tel: 514-918-5677 Fax: 450-965-9260 <u>contact@innovia-</u> <u>biopharma.com</u> <u>http://www.innovia-</u> <u>biopharma.com</u>	Pharmaceuticals Veterinary Drugs Medical Devices Cosmetics Over-the-counter Products Natural Health Products Food & Feed	<ul> <li>Product labelling &amp; Packaging assessment</li> <li>Establishment/Site &amp; product Licensing</li> <li>QMS implementation</li> <li>Internal &amp; External Audits</li> <li>Compliance &amp; document management</li> <li>Temperature mapping &amp; Instrument calibration (with partner)</li> <li>Stability program management</li> </ul>	Canada United States Europe	
International Food Focus Ltd. 211 Carlton Street Toronto, ON M5A 2K9	Carol T. Culhane Tel: 416-924-3266 Fax: 416-924-2726 <u>cculhane@foodfocus.on.ca</u> <u>www.foodfocus.on.ca</u>	Food Ingredients Novel Foods Novel Fibres Processed Food Infant Formula Natural Health Products Animal Feed Supplements	<ul> <li>Pre-commercialization and pre- market notification: assimilation of scientific dossiers for regulator review</li> <li>Post-commercialization label creation (including French translation) or audit</li> <li>Regulatory and market impact studies</li> <li>Learning &amp; Development – seminars and workshops</li> </ul>	Canada USA EU	



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Intrinsik Corp. 6605 Hurontario Street Suite 500 Mississauga, Ontario L5T 0A3	Katharine Manson Tel: 905-364-7800 ext. 209 Fax: 905-364-7816 <u>kmanson@intrinsik.com</u> <u>www.intrinsik.com</u>	Pharmaceuticals Biologics Veterinary Drugs Medical Devices Cosmetics Over-the-counter Products Natural Health Products	• Intrinsik Corp. is a specialized group of regulatory and toxicology professionals with backgrounds from large and emerging pharmaceutical, biotechnology companies, and consulting firms. Cumulatively, our team provides your company with years of relevant experience to help with all stages of drug development.	Canada United States Europe Asia Australia	
JohnSimon & Associates Ltd. 2438 Martell Crescent NW Edmonton Alberta, T6R 0M6 Canada	John Simon Tel: 780-975-0095 <u>John@JohnSimon.ca</u> <u>www.johnsimon.ca</u>	Pharmaceuticals Biologics Medical Devices Cosmetics Over-the-counter Products Natural Health Products	We provide site licensing and product licensing support for new and established companies.	Canada United States	
Julie Rooney 1723 des Écores Terrebonne Quebec, J6X 3K9 Canada	Julie Rooney Tel: 438-397-6956 Fax: 450 492-6901 <u>rooneyjuliej@gmail.com</u>	Cosmetics Natural Health Products	NPN licence, Cosmetics and Food	Canada	
K Friedman Consulting 537 Bedford Park Avenue Toronto, Ontario M5M 1K4 Canada	Tel: 416-783-9394 <u>karenfriedman@rogers.com</u> <u>http://www.kfriedmanconsulting</u> <u>.com</u>	Pharmaceuticals Cosmetics Over-the-counter Products Natural Health Products	• Strategic regulatory consulting for registration of drug products, natural health products and cosmetics. Good manufacturing practices services for registration of site licenses, drug establishment licenses.	Canada	



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Lockhart Regulatory Services Inc. 1860 Appleby Line, Suite 348 Burlington, Ontario L7L 7H7	Marilyn Lockhart Tel: 289-270-5376 Fax: 289-270-5376 <u>mplockhart@sympatico.ca</u>	Pharmaceuticals Medical Devices Over-the-Counter Products Natural Health Products	<ul> <li>Experienced</li> <li>Results-Oriented</li> <li>Recognized</li> <li>Regulatory and Quality</li> </ul>	Canada United States	
Mapi Life Sciences Canada Inc. (formerly CanReg Inc.) 4 Innovation Drive Dundas, ON L9H 7P3	Hetal Mokashi Tel: 905-690-5540 Fax: 905-689-1465 <u>hmokashi@mapigroup.com</u> <u>www.mapigroup.com</u>	Pharmaceuticals Biologics Medical Devices Cosmetics Over-the-counter Products Natural Health Products	<ul> <li>Regulatory Affairs, CMC and QA services</li> <li>eCTD &amp; NeeS (preparation, management and hosting)</li> <li>Pharmacovigilance/Medical Information</li> <li>CTAs/Canadian agent services</li> <li>Canadian Importer of Record</li> <li>Quality systems (GMP, ISO13485)</li> <li>Environmental regulatory</li> </ul>	Canada United States Europe Asia Africa Australia Latin America	
MarcM Consulting Canada 172 Mausser Avenue Kitchener, ON N2M 3K7	Marcela Saad Tel: 519-579-0821 Fax: 519-579-0821 <u>marcmconsulting@marcmconsulting.c</u> <u>a</u> <u>www.marcmconsulting.ca</u> <u>http://ca.linkedin.com/pub/marc ela-saad/7/30b/bb3</u>	Pharmaceuticals Biologics Veterinary Drugs Medical Devices Cosmetics Over-the-counter Products Natural Health Products	<ul> <li>Regulatory strategy, product registrations &amp; post-market changes</li> <li>Clinical trial &amp; establishment license applications</li> <li>Quality System &amp; GMP/GCP/ISO compliance</li> <li>Extensive expertise in the Americas in English, Portuguese &amp; Spanish</li> </ul>	Canada United States Latin America Europe	



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Address		Product Areas:	Services:	Countries:
McCarthy Consultant Services, Inc. 1151 Gorham Street Unit 8 Newmarket, Ontario L3Y 8Y1 Canada	Stephen McCarthy Tel: 905 836 0033 Fax: 905 836 0006 <u>smccarthy@mccarthyconsultant.com</u> <u>www.mccarthyconsultant.com</u>	Pharmaceuticals Biologics Veterinary Drugs Medical Devices Cosmetics Over-the-counter Products Natural Health Products	<ul> <li>Shaped by the belief that sound Regulatory management is the key to business success, MCSI has evolved into an industry leader across Canada and throughout the world.</li> </ul>	Canada United States Europe Asia
Normand Robichaud Services conseils inc. 4025 chemin Sainte-Foy Quebec, Quebec G1Y 1T7	Normand Robichaud Tel: 418-650-5628 normand.robichaud@videotron.ca www.normandrobichaud.com	Pharmaceuticals Medical Devices Cosmetics Over-the-counter Products Natural Health Products	<ul> <li>Services conseils en Bonnes Pratiques de Fabrication (BPF)</li> <li>Systèmes Qualité</li> <li>Audits Qualité</li> <li>Conformité pour l'industrie pharmaceutique, cosmétique, des biotechnologies et des produits de santé naturels</li> </ul>	Canada United States Europe
Nucro_Technics 2000 Ellesmere Rd. Unit #16 Scarborough, ON M1H 2W4 Canada	Constantine Fanaras Tel: 416-438-6727 Fax: 416-438-3463 <u>cfanaras@nucro-technics.com</u> <u>http://www.nucro-technics.com</u>	Pharmaceuticals Biologics Veterinary Drugs Medical Devices Cosmetics Over-the-counter Products Natural Health Products	<ul> <li>Regulatory Affairs, CMC, and QA/QC Consulting Services</li> <li>Pharmacovigilance / Medical Information</li> <li>Cosmetic Notifications / Labelling Reviews</li> <li>Preclinical Toxicology, Bioanalytical, Genetic Toxicology Testing Services</li> <li>Analytical Chemistry and Microbiology Testing Services</li> <li>Warehouse Services</li> <li>GMP/GLP/ISO 9001:2008 Compliant</li> </ul>	Canada United States Europe Asia Africa Australia Latin America



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Pharmaffair Inc. 52 Sandfield Rd. Toronto, ON M3B 2B7	Maha Tawashi Tel: 416-444-8090 Fax: 416-444-4246 <u>pharmaffair@rogers.com</u> <u>www.pharmaffair.ca</u>	Pharmaceuticals Biologics Medical Devices Cosmetics Over-the-counter Products Natural Health Products	<ul> <li>Preparation, filing &amp; maintenance of submissions to HC for pharmaceuticals, biologics, NHPs, medical devices (Class II, III &amp; IV) and cosmetics according to HC/ICH guidelines.</li> </ul>	Canada	
PharmEng Technology 23 Lesmill Road, Suite 410 North York, Ontario M3B 3P6 Canada	Alex Della Mora Tel: 416-385-3922 Ext. 120 <u>bd@pharmeng.com</u> <u>http://www.pharmeng.com</u>	Pharmaceuticals Biologics Veterinary Drugs Medical Devices Cosmetics Over-the-counter Products Natural Health Products	Regulatory Affairs, Quality Systems, Commissioning & Qualification, Validation, Engineering, Training.	Canada United States Asia	
PRTox Consulting Inc. 922 Pezer Cres Saskatoon Saskatchewan, S7S 1J8	Daniel Bechtel Tel: 306-262-6271 <u>info@prtox.ca</u> <u>www.prtox.ca</u>	Pest Control Products Plants with Novel Traits Pharmaceuticals Veterinary Drugs Cosmetics Over-the-counter Products Natural Health Products New Chemical Notification	<ul> <li>Regulatory guidance, dossier preparation and submission.</li> <li>Toxicology study development and management.</li> <li>Scientific guidance for analytical, environmental and human health regulatory documentation.</li> <li>Facility Compliance (Audit/GCP/GLP/GMP/SOP's)</li> </ul>	Canada	



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Q&C 2550 Argentia Road, Suite 119 Mississauga ON L5N 5R1 Canada	Jennifer Cazabon Tel: 905-363-1182 Fax: 905-542-7981 <u>jcazabon@qualityandcompliance.com</u> <u>www.qualityandcompliance.com</u>	Pharmaceuticals Biologics Veterinary Drugs Medical Devices Cosmetics Over-the-counter Products Natural Health Products API Vaccines	<ul> <li>Comprehensive regulatory assessment, strategy and guidance for drugs, APIs, natural health products and medical devices.</li> <li>Professional guidance and practical assistance for the importation of drugs, APIs, NHPs and medical devices.</li> </ul>	Canada United States Europe Asia Australia Latin America Mexico Russia Brazil	
RaQa Consulting Inc. 4 Robert Speck Parkway 15 <sup>th</sup> Floor Mississauga, ON L4Z 1S1	Sandra Ireland Tel/Fax: 1-866-697-7272 info@raqaconsulting.ca www.raqaconsulting.ca	Medical Devices Cosmetics Pharmaceuticals Over-the-counter Products Natural Health Products Foods	<ul> <li>Complete Business Solutions and Project Management for manufacturing/importing and distributing drugs, medical devices, cosmetics and NHP's.</li> <li>Drug/Device Establishment and Site Licensing</li> <li>Regulatory submissions for Drugs, medical devices and natural health products (NHPs)</li> <li>Quality compliance, audits (GMP, ISO) and document management.</li> </ul>	Canada United States	
Redstone Health Group Inc. 2125 Galena Cres. Oakville, ON L6H 4A9 Canada	Karen Feltmate Tel: 905-842-4230 Fax: 905-338-8970 <u>kfeltmate@redstonehealthgroup.com</u> <u>www.redstonehealthgroup.com</u>	Pharmaceuticals	We provide strategic and operational regulatory support that align and enhance your greater business strategy.	Canada	



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Company Name / Address	Contact Information	Summary of Services (see Notes)			
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Reg-Affairs & QualiPractixis Inc. 22 King Street South, Waterloo, ON N2J 1N8, Canada	Femi Adeoye Tel: (226) 780-0216 ext. 101 femi.adeoye@reg-affairsqp.com www.reg-affairsqp.com	Pharmaceuticals Medical Devices Over-the-counter Products Natural Health Products Cosmetics	<ul> <li>Regulatory Submissions for Drugs (Rx &amp; OTC), NHPs &amp; Medical Devices</li> <li>QA, GMP &amp; ISO 13485/FDA QSR Consulting and Auditing for drugs, medical devices &amp; NHPs</li> <li>Cosmetics Label Review &amp; notification</li> <li>Pharmacovigilance &amp; Clinical Trial Consulting</li> <li>EU Responsible Person &amp; Authorized Representatives services</li> </ul>	Canada United States Europe Nigeria	
RegCon Solutions (Canada) Inc. Mississauga, ON L5A 3Z2 Canada	Paul Varady Tel: (289) 724-2798 info@regconsolutions.ca www.regconsolutions.ca	Pharmaceuticals Veterinary Drugs Natural Health Products Cosmetics eCTD Publishing	<ul> <li>Straight forward, efficient, no nonsense provider of regulatory services and solutions.</li> <li>Initial consultations at no cost</li> <li>Capped project based rates that encourage interaction and prevent budget overruns. Rates include responses to Health Canada/FDA at no extra cost</li> <li>Project management from strategy planning through to post approval.</li> <li>eCTD component and submission publishing with Gateway support - Fast, efficient, reasonably priced eCTD publishing services. Hourly or flat rate. Support for Consultants available.</li> <li>Specializing in challenging projects</li> <li>Domestic and foreign company (agent) support.</li> </ul>	Canada United States	



2017 List of Consultants (see Disclaimer)					
Company Name / Address	Contact Information	Summary of Services (see Notes)			
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Regulatory Solutions Inc. (RSI) 21 Parr Blvd, Unit 1C Caledon, ON L7E 4G3	Jane P. Costaris Tel: 905-857-3132 ext. 101 Fax: 905-857-3816 jane@regulatorysolutions.ca www.regulatorysolutions.ca	Pharmaceuticals Medical Devices Natural Health Products	<ul> <li>Since May 2001, RSI has specialized in timely, innovative and strategic Regulatory Approvals from Health Canada for drug products ((S)ANDS, (S)NDS, DINA, SRTD, Post-NOC), medical devices (medical device license applications and amendments, MDEL) and natural health products (PLA, post-licensing, SL)</li> <li>Initial DEL approval and ongoing QA/QC support (GMP, SOPs, warehouse)</li> <li>Provincial Formulary Submissions</li> <li>eCTD Submissions</li> <li>Monitor BE studies</li> <li>Pharmacovigilance</li> <li>Compliance to PLL regulations and label design</li> <li>Customized Regulatory Solutions to suit your specific business objectives.</li> </ul>	Canada	



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Regxia Inc. Unit 1C 64 Jardin Drive Vaughan, ON L4K 3P3	Cameron McGregor Tel: 416-620-5236 Fax: 416-620-0261 <u>mcgregor@regxia.com</u> <u>www.regxia.com</u>	Pharmaceuticals Biologics Veterinary Drugs Medical Devices Over-the-counter Products	<ul> <li>Regulatory Affairs</li> <li>Dossier Compilation &amp; Management</li> <li>eCTD (preparation, management and publishing)</li> <li>CMC</li> <li>Clinical &amp; Quality services</li> <li>Clinical Monitoring &amp; Management</li> <li>Pharmacovigilance</li> <li>SOPs &amp; Reporting</li> <li>CTAs, IND, NDS, ANDS, etc.</li> </ul>	Canada United States Europe	
SMI Solutions 50 Alliance Blvd. Barrie, Ontario L4M 5K3 Canada	Tish Whitehead Tel: 705-720-1902 Ext. 342 info@smi-solutions.com http://www.smi-solutions.com/	Medical Devices	<ul> <li>Medical device regulatory strategy</li> <li>Medical device registration and approval</li> <li>Medical Device Establishment licence registration</li> <li>Labelling compliance</li> <li>Quality systems compliance</li> <li>Medical device reporting requirements</li> <li>Recall navigation</li> <li>Post market surveillance</li> <li>Canadian representation</li> </ul>	Canada United States Europe	



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Company Name /	Contact Information	Summary of Services (see Notes)		
Address		Product Areas:	Services:	Countries:
Stan North Consultation 166 Promenade Sheraton Montreal-Ouest Quebec, H4X 1N4	Stan North, M.Sc. Tel: 514-577-5913 info@stannorthconsultation.co <u>m</u> www.StanNorthConsultation.com	Pharmaceuticals Biologics Medical Devices Over-the-counter Products Natural Health Products Cosmetics	<ul> <li>Regulatory consulting for the pharma, medical device and biotech sectors</li> <li>Clinical and CMC submissions</li> <li>CTAs</li> <li>Project management</li> <li>Product monographs and labeling</li> <li>Regulatory guidance and strategy</li> <li>We offer quality service, flexibility and customer-focus with over 20 years of industry experience</li> </ul>	Canada
SYLLA CONSEILS INC. 2149 Lincourt Longueuil, Quebec J4N 1N8	Sylvie Lachance Tel: 450-332-0928 Cell:514-823-0928 Fax:450-332-0928 <u>sylvie-lachance@videotron.ca</u> <u>www.syllaconseils.com</u>	Pharmaceuticals Veterinary Drugs Medical Devices Cosmetics Over-the-counter Products Natural Health Products	<ul> <li>Regulatory Affairs</li> <li>DIN,NPN applications &amp; Medical device licences</li> <li>Establishment/Site Licensing</li> <li>QC/QA implementation &amp; follow-up</li> <li>GMP's, GLP's,SOP's training</li> <li>Internal &amp; External Audits</li> <li>Liaison with Health Canada &amp; FDA during inspection</li> <li>Packaging review</li> </ul>	Canada United States Europe
Therapeutic Products Inc. 1269 Centre Rd. Hamilton, ON L8N 2Z7	Anne Tomalin Tel: 905-690-4343 Fax: 905-690-3202 <u>atomalin@tpireg.com</u>	Pharmaceuticals Biologics Over-the-counter Products Natural Health Products Medical Devices	<ul> <li>Regulatory consulting</li> <li>Advertising Review - DTCA/DTCI Consultation</li> <li>PAAB review consultation</li> <li>Quality Assurance</li> </ul>	Canada United States Europe



2017 List of Consultants (see Disclaimer)				
Company Name / Address	Contact Information	Summary of Services (see Notes)		
		Product Areas:	Services:	Countries:
Tho Huynh Consultant 5415 Baillargeon St-Hubert, Quebec J3Y 2B2 Canada	Tho Huynh, Ph.D. Tel: 450-656-4301 <u>tho.huynh2014@gmail.com</u>	Pharmaceuticals Biologics Veterinary Drugs Over-the-counter Products Natural Health Products	<ul> <li>40 years' experience in pharmaceutical GMP areas including 13 years as Health Canada drug GMP inspector.</li> <li>GMP audits of API and finished dosage form suppliers, specially sterile and aseptic process manufacturing.</li> <li>QA/QC systems, procedures</li> </ul>	Canada United States Europe Asia Australia Latin America
THT Health Communications 15 Woodend Drive Carlisle, Ontario L0R 1H2 Canada	Tracy Howard-Tripp         Tel: (905) 690-9746         Fax: (905) 690-9665         tracy.howardtripp@sympatico.ca         http://www.medicalregulatoryc         onsulting.com	Pharmaceuticals Biologics	<ul> <li>Qualification/ validation, training</li> <li>Expert regulatory/medical writing consultant.</li> <li>Over 20 years' experience preparing, submitting, and negotiating clinical and marketing applications.</li> <li>Specialized medical writing expertise in the preparation of documents for drug product development.</li> </ul>	Canada



2017 List of Consultants (see Disclaimer)					
Company Name / Address	Contact Information	S	ummary of Services (see Notes)		
		Product Areas:	Services:	Countries:	
VG Solutions Inc. (Grieb Consulting) 1060 du Canna Laval, QC H7X 3W4	Victoria Grieb Tel: 450-314-3545, Tel: 514-651-0465 Fax: 450-314-3585 <u>vgrieb@vgsolutions.ca</u>	Pharmaceuticals Medical Devices Cosmetics Over-the-counter Products Natural Health Products Food	<ul> <li>Regulatory affairs for cosmetics, OTC drugs, NHPs and food</li> <li>DIN, NPN applications, Medical device licenses</li> <li>Liaison – Health Canada</li> <li>Regulatory, SOP training</li> <li>GMP training and inspections, QA/QC</li> <li>Packaging review</li> <li>Environmental compliances</li> <li>Certificates of Free Sale (ITCs)</li> <li>English or French, including translations</li> </ul>	Canada	
White Owl Global Services Ltd. 610 Ford Drive, Suite 101 Oakville, Ontario L6J 7W4 Canada	Selma Djukic Tel: (905) 829-4546 Fax: (905) 829-5754 <u>info@whiteowlglobal.com</u> <u>www.whiteowlglobal.com</u>	Pharmaceuticals Biologics Medical Devices Over-the-counter Products Natural Health Products Radiopharmaceuticals Veterinary Drugs Active Pharmaceutical Products (APIs)	<ul> <li>Expert strategic technical &amp; project management solutions: development, manufacturing, packaging, analytical (Phase I through validation, commercialization / post-commercial activities)</li> <li>All dosage formats</li> <li>Preparation / filing of Regulatory Submissions</li> <li>Free initial consultation</li> </ul>	Canada United States Europe ROW	



## **List of Consultants**

The list comprises consulting companies whose primary focus is Regulatory Affairs, Clinical Research, Quality Control or Compliance (GCP, GLP, and GMP) for pharmaceuticals, biologics, veterinary drugs, medical devices, cosmetics, over-the-counter products, or natural health products.

Companies are listed alphabetically by company name.

List of Acronyms: DIN = Drug Identification Number DMF = Drug Master File GCP = Good Clinical Practice GLP = Good Laboratory Practice GMP = Good Manufacturing Practices NHP = Natural Health Product QA = Quality Assurance QC = Quality Control RA = Regulatory Affairs SOP = Standard Operating Procedures

## Notes:

<u>Clinical Trials Research</u> includes conduct of trials (Phases I-IV), bioanalytical, data management and statistical services. <u>GCP</u> includes guidance on requirements, preparation of SOPs, conduct of audits and GCP training. <u>GLP</u> includes guidance on requirements, preparation of SOPs, conduct of audits and GLP training. <u>GMP</u> includes guidance on requirements, preparation of SOPs, conduct of audits and GMP training. <u>Product Development</u> includes guidance on requirements for moving through the therapeutic product development process. <u>Quality Assurance/Quality Control (QA/QC)</u> includes arranging appropriate product testing and release.



Regulatory Affairs (RA) comprises review, assessment and preparation of appropriate regulatory documentation. Expertise in Clinical and/or Quality

(chemistry and manufacturing) aspects is specified.

<u>Toxicology</u> includes nonclinical drug development and safety programs.

## **Disclaimer:**

CAPRA / ACPR maintains this List of Consultants as a service to industry and to the regulatory authorities. The individual companies have provided the information on the list for presentation in a standard format. CAPRA / ACPR does not endorse any of the consultants on the list.