Collaborative Groups	2025-2030 Focus Areas	Required Expertise [Any of the following]	Preferred Expertise [Any of the following]
BIOLOGICS	Therapeutic Peptides, Oligonucleotides and Complex Carbohydrates	Understanding of the characterization, analytical and/or bioassays, of one or more of the 3 modalities (oligonucleotides, peptides or complex carbohydrates). The candidate should have experience in one or more of the following areas for one or more of these modalities: setting specifications, manufacturing processes and quality control, and methods development and validation.	The candidate should have experience in one or more of the following areas for one or more of these modalities: setting specifications, manufacturing processes and quality control, formulation development, and methods development and validation; characterizing synthetic and/or recombinant therapeutic peptides and methods to monitor impurities; microbial and HPLC-based assay methods, methods to monitor control impurities, and modernizing release methods. Understanding of USP revision process. Understanding of the US and international regulations for one or more of these 3 modalities.
	Therapeutic Proteins	The expert volunteer should have experience in one or more of the following areas: analytical characterization of protein therapeutics, bioassay development, manufacturing processes and quality control, methods development and validation. Experience with characterization or production of one or more of the following product types of Insulins, enzymes, and monoclonal antibodies.	The expert volunteer should have experience in one or more of the following areas: formulation development, methods to monitor control impurities. Understanding of USP revision process. Understanding of the US and international regulations for protein therapeutics.
	Vaccines	The expert volunteer should have experience in one or more of the following areas for one or more vaccine modality (mRNA, viral vectored, glycoconjugate, protein subunit, inactivated, attenuated): analytical characterization, manufacturing processes and quality control, methods development and validation.	The expert volunteer should have experience in one or more of the following areas formulation development, methods to monitor control impurities. Understanding of USP revision process. Understanding of the US and international regulations for protein therapeutics. Quality control of raw and starting materials.
	Cell and Gene Therapies	The expert volunteer should have experience in one or more of the following areas for one or more class of cell or gene therapies: analytical characterization, bioassay development, manufacturing processes and quality control, methods development and validation. Experience with characterization or production of one or more of the following product types of CAR-T, AAV, and LV based therapies.	The expert volunteer should have experience in one or more of the following areas formulation development, methods to monitor control impurities. Understanding of USP revision process. Understanding of the US and international regulations for cell and gene therapies. Quality assessment of raw and starting materials.
Excipients	Excipient Monographs 1	Knowledge of excipient manufacturing, development, and supply chain distribution, Analytical chemists (chromatography, spectophotometry). Knowledge of US and international drug development and manufacturing regulations and ICH, knowledge of reference material standards development including digital RS.	Supply chain distribution, expertise in either simple organic / inorganic excipients, or fixed or essential oils.

	Excipient Monographs 2	Working knowledge of advanced analytics- SEC/GPC/MALLS/ELSD, NMR and advanced chemometrics used in the formulation of excipients. FDA / CGX PSGs, and international regulations, ICH guidances used in the formulation and manufacture of complex drug formations (injectibles, opthalmics, inhalation).	Knowledge of novel excipients and US FDA and international regulatory activities. Knowledge of PDG excipient workplan.
	Excipient Chapters	Analytical expertise in the physical and chemical characterization of excipients including chromatography and spectroscopic analytics. International Excipient GMPs, supply, and GDPs.	Clinical development of excipients (pharm/tox, in silico, in vitro, predictive modeling)
Food Ingredients, Dietary Supplements, Herbal Medicines	BDSHM	Prior experience working in an analytical chemistry laboratory is a plus. Knowledge of sample preparation, data analysis, and troubleshooting. Precise and accurate execution of experiments and measurements. Familarity with Liquid Chromatography (H/UPLC) Gas Chromatography Planar Chromatography (HPTLC) Vibrational Spectroscopy (IR/Raman) Nuclear Magnetic Resonance (NMR/qNMR) Atomic Spectroscopy (flame/plasma) and light scattering techniques Ultraviolet/Visible Spectroscopy (UV/Vis) X-Ray Fluorescence and Diffraction (XRF/XRD) Karl Fischer Titration Method Mass Spectrometry Techniques Wet Chemistry Methods	Herbalist, physician who prescribes botanicals and traditional medicines

	NBDS	Prior experience working in an analytical chemistry laboratory is a plus. Knowledge of sample preparation, data analysis, and troubleshooting. Precise and accurate execution of experiments and measurements. Familarity with Liquid Chromatography (H/UPLC) Gas Chromatography Planar Chromatography (HPTLC) Vibrational Spectroscopy (IR/Raman) Nuclear Magnetic Resonance (NMR/qNMR) Atomic Spectroscopy (flame/plasma) and light scattering techniques Ultraviolet/Visible Spectroscopy (UV/Vis) X-Ray Fluorescence and Diffraction (XRF/XRD) Karl Fischer Titration Method Mass Spectrometry Techniques Wet Chemistry Methods	Clinical or clinical pharmacology experience
	DSAEL	Contribute to evidence-based toxicology reviews, perform in silico toxicology tests, collaborate on integrative medical science projects, and assist with regulatory risk assessment. Additionally, participate in surveillance and adverse effect monitoring, helping us identify potential health risks. Elevating safer environments and informed decision-making.	Clinical experience utilizing herbal medicines and dietary supplements
	FI	Contribute to the development and evaluation of special nutrition ingredients, including dietary proteins, amino acids, and human milk oligosaccharides (HMOs). The expertise should include: Statistics and Experimental Design, Microbiology and Analytical Methods, Regulatory Knowledge and Quality Assurance and Authenticity Testing.	Experience in analytical methods like next-generation sequencing, NMR. Specialized expertise in botanical-derived ingredients, especially focusing on authenticity and food fraud prevention

Healthcare Quality & Safety	Personalized Medicines	The expert volunteer would have specialized knowledge in the following areas: Pharmacogenomics and Genomic Sciences: Understand genetic impacts on medication responses. Digital Health Technology: Develop software and devices for health management. AI and Machine Learning: Integrate AI into clinical settings. Clinical Pharmacology: Ensure patient-centered standards. Bioinformatics and Data Science: Analyze complex biological data. Regulatory Affairs and Ethics: Guide compliance and ethical data use. Health Economics: Evaluate cost-effectiveness. Patient Advocacy: Prioritize patient needs.specialized knowledge in the following areas:	In this role, the expert volunteer will contribute to shaping the future of healthcare by promoting patient-centered, data-driven approaches. Your expertise will help bridge the gap between scientific innovation and patient well-being through the following: Health Policy and Patient Rights Medical Ethics Healthcare Economics Medical Sociology or Anthropology Regenerative Medicine Environmental Health. Legal Expertise in Intellectual Property Consumer Health Informatics Clinical Trial Design and Innovation Patient Advocacy and Community Engagement
	Healthcare Safety, Quality & Nomenclature	Experience (>3 years) with pharmacopeias and chemical or drug nomenclature Experience (> 3 years) with medication / patient safety and education Experience (>3 years) in pharmaceutical industry Experience in healthcare settings (e.g. outpatient, long-term care, inpatient, clinic) Experience (>3 years) with formulary development and review Working experience (> 3 years) with healthcare beneficiaries and healthcare marketplace Expertise (>3 years) in drug information Expertise (>3 years) in Medicare healthcare policy Expertise in health literacy Global experience	PharmD/ BS. Pharmacy PhD - Chemistry, Medicinal Chemistry PhD - Pharmacology, Pharmaceutical Science BS. Nursing / Doctor of Nursing / ARNP MD/PhD
	Healthcare Information and Technology	Demonstrated technical administrative experience with electronic health record clinical applications, including but not limited to master file maintenance and clinical build (i.e. smart sets, order sets, documentation flowsheets) Subject matter expert (SME) of messaging standards Experience with meaningful use Experience with vocabulary standards of electronic health records (e.g. SNOMED CT, LOINC, RXNorm) Experience developing Health IT software Experience with global standards for the transfer of clinical health data between applications including HL7	Bachelor's degree RN, ARNP, PA, PharmD, BS Pharm, MD Experience in systems deployment as a clinical analyst, business analyst, or systems analyst Epic / Cerner Certification NCPDP standard proficiency Experience with the integration of national HIT interoperable framework

		and FHIR standards Healthcare industry experience preferably in a hospital or major medical center clinical setting	
	Compounding	PharmD/ BS. Pharmacy/MD/DVM/BSN PhD or other advanced qualifications - Chemistry, Medicinal Chemistry, Drug stability PhD or other advanced qualifications- Pharmacology, Pharmaceutical Science, toxicology Medical microbiology Environmental engineering, compounding facility design cGMP, chemistry and manufacturing controls, compounding/manufacturing technologies, process & technology validation Parenteral nutrition	Experience with USP processes, stakeholder engagement and compounding regulation in the USA and beyond Compounding formulation development and drug stability analysis and evaluation Experience with parenteral nutrition prescribing, compounding, ordering, storage, transportation, administration Experience in developing and implementing protocols to minimize personnel exposure to and environment control of hazardous drugs in healthcare settings Designing or setting up compounding facilities Sterile and nonsterile compounding in various settings Developing and implementing quality assurance and quality control protocols in compounding practice Global experience
Small Molecules	Small Molecules Therapeutic Areas 1 (Antibiotics, Antimicrobials & Antivirals)	An expert volunteer working with small molecules related to antibiotic, antiviral, and antimicrobial drug substance and drug product monographs, will be specialized in: Pharmacology Knowledge Biochemistry Understanding Research Skills Analytical Skills Laboratory Experience with hands-on experience with assays, stability studies, and quality control. Regulatory Knowledge Knowledge of guidelines from agencies such as FDA and others Quality Assurance to ensure compliance with Good Manufacturing Practices (GMP) and quality standards. Technical Writing	Understanding spectroscopic techniques (such as UV-Vis, IR, NMR, MS, ICP) and chromatographic methods (HPLC, GC). Method Development: Ability to develop and validate analytical methods specific to small molecules. This includes optimizing parameters, ensuring sensitivity, and robustness. Mass Spectrometry (MS): Familiarity with mass spectrometry is essential. MS is used to identify and characterize small molecules, drugs, metabolites, and larger molecules like proteins and peptides. Chemoinformatics: Utilize computational tools for predicting properties, designing molecules, and virtual

	Small Molecules Therapeutic Areas 2 (Cold, Cough & Analgesic)	An expert volunteer working with small molecules related to cardiovascular, cough, cold, and analgesic drug substance and drug product monographs will be specialized in The mechanisms of action, pharmacokinetics, and pharmacodynamics of cardiovascular drugs, cough suppressants, cold remedies, and analgesics. Research Skills Analytical Skills Laboratory Experience with hands-on experience with assays, stability studies, and quality control. Regulatory Knowledge Knowledge of guidelines from agencies such as FDA and others Quality Assurance to ensure compliance with Good Manufacturing Practices (GMP) and quality standards. Technical Writing	screening. Expertise in Use of GC 81 (Microbial Assay for Potency): Proficient in conducting microbial assays for potency, specifically using USP General Chapter 81 (GC 81). Pharmacokinetics (PK): Understanding PK principles helps assess drug absorption, distribution, metabolism, and excretion. Formulation Science: Knowledge of formulating small molecules into various dosage forms. Regulatory Compliance: Awareness of global regulatory guidelines related to small molecule development. Problem-Solving: Strong research skills for troubleshooting and addressing challenges during drug development.
	Small Molecules Therapeutic Areas 3 (Gastrointestinal, Renal, Endocrine & Oncology)	Understand the mechanisms of action, pharmacokinetics, and pharmacodynamics of small molecules used in these therapeutic areas. Familiarity with drug interactions and adverse effects. Research Skills Analytical Skills Laboratory Experience with hands-on experience with assays, stability studies, and quality control. Regulatory Knowledge Knowledge of guidelines from agencies such as FDA and others Quality Assurance to ensure compliance with Good Manufacturing Practices (GMP) and quality standards. Technical Writing	
	Small Molecules Therapeutic Areas 4 (Psychiatric, Psychoactive, Neuromuscular, Radiopharmaceutical & Non-Radioactive Imaging Agents)	An expert volunteer should be highly specialized in Monographs related to medications used for mental health conditions including antidepressants, antipsychotics, anxiolytics, and mood stabilizers. Psychoactive Agents - Monographs for drugs affecting the central nervous system such as stimulants, sedatives, and hallucinogens. Neuromuscular Agents which includes muscle relaxants, neuromuscular blockers, and treatments for neuromuscular diseases. Radiopharmaceuticals and Imaging Agents for radioactive and non-radioactive compounds used in medical imaging.	

		Includes contrast agents, radiotracers, and diagnostic tools.	
	Small Molecules Therapeutic Areas 5 (Pulmonary, Aerosol, Inhalation & Steroids)	Experienced in the following areas Pulmonary Agents - drugs specifically designed for respiratory conditions - bronchodilators, anti-inflammatory agents, and medications for asthma and chronic obstructive pulmonary disease (COPD). Aerosol and Inhalation Products - formulations delivered via inhalation. Includes metered-dose inhalers (MDIs), dry powder inhalers (DPIs), and nebulizers. Steroidal drugs used for various purposes, including anti-inflammatory effects. Commonly used in conditions such as asthma, allergies, and autoimmune diseases.	
	Small Molecules Therapeutic Areas 6 (Cardiovascular, Ophthalmology, Otic, Dermatology & Veterinary Products)	Highly experienced in Cardiovascular Agents - drugs targeting the cardiovascular system. Includes antihypertensives, antiarrhythmics, lipid-lowering agents, and vasodilators. Ophthalmology Products focusing on eye health and vision. Includes treatments for glaucoma, dry eye, and other ocular conditions. Otic (Ear) Products - Designed for ear-related issues. Includes treatments for ear infections, wax removal, and inflammation. Dermatology Agents - Includes topical creams, ointments, and systemic medications for dermatological disorders. Veterinary Products -specifically for animals. Includes medications for pets and livestock.	
General Chapters	Dosage Forms	Extensive experience in handling various complex product development, working experience on formulation analytical characterization techniques etc. Complex Generics Analytical procedures and manufacturing of all dosage forms	Regulatory exposure for handling various complex products Complex Generics In-process controls for all dosage forms

	Chemical Analysis	Utilize chromatographic techniques (e.g., HPLC, GC) for separating and analyzing complex mixtures of compounds. Apply spectroscopic methods (e.g., UV-Vis, IR, NMR) to study molecular structures and interactions. Understand water quality standards for pharmaceutical use. Ensure water purity in drug manufacturing processes. Employ methods (e.g., titration, gravimetric analysis) to assess drug identity, purity, and potency. Handle and analyze data accurately in compliance with regulatory standards. Evaluate the safety and toxicity of pharmaceutical compounds. Use nuclear magnetic resonance for structural characterization of solid materials. Quantify compounds using NMR spectroscopy. Apply sustainable methods to minimize environmental impact	International standards harmonization Regulatory GMP
	Microbiology	Experience in assessing pyrogenic substances and their impact on immune cells. Knowledge of MAT principles for detecting endotoxins. Familiarity with BET methods using recombinant reagents. Ability to validate and perform endotoxin testing. Stay updated on innovative microbiological techniques for efficient testing. Understand their applications in pharmaceutical quality control. Develop strategies to prevent contamination during drug manufacturing. Ensure sterility of pharmaceutical products. Assess microbial load in raw materials and finished products. Implement environmental monitoring to maintain cleanliness. Validate analytical methods for microbial testing. Ensure accuracy and reliability of results. Compare different methods for consistency and reliability. Optimize testing protocols.	Dietary supplements and food ingredients Cell and gene therapy Biologics Molecular Biology Compounding Preparation

	Packaging and Distribution	Analytical chemistry: Proficiency in various analytical techniques, including chromatography (LC, GC, IC), mass spectrometry (MS), spectroscopy (UV, IR, NMR), and wet chemical methods. This expertise is crucial for identifying and quantifying extractable and leachable compounds. Material/solution interactions: Understanding of the principles governing interactions between materials (such as packaging, containers, and manufacturing equipment) and pharmaceutical solutions, including knowledge of migration modeling and drug binding. Regulatory compliance: Familiarity with regulatory guidelines and requirements from agencies such as the FDA, ICH, USP, and other global regulatory bodies regarding extractables and leachables assessments for pharmaceutical products. Method development and validation: Skill in developing and validating analytical methods specific to extractables and leachables testing, ensuring accuracy, precision, and reliability of results. Instrumentation: Proficiency in operating and maintaining advanced analytical instruments used in the detection and analysis of extractables and leachables, including specialized chromatography and spectroscopy equipment.	Analytical chemistry: Proficiency in various analytical techniques, including chromatography (LC, GC, IC), mass spectrometry (MS), spectroscopy (UV, IR, NMR), and wet chemical methods. This expertise is crucial for identifying and quantifying extractable and leachable compounds. Material/solution interactions: Understanding of the principles governing interactions between materials (such as packaging, containers, and manufacturing equipment) and pharmaceutical solutions, including knowledge of migration modeling and drug binding. Regulatory compliance: Familiarity with regulatory guidelines and requirements from agencies such as the FDA, ICH, USP, and other global regulatory bodies regarding extractables and leachables assessments for pharmaceutical products. Method development and validation: Skill in developing and validating analytical methods specific to extractables and leachables testing, ensuring accuracy, precision, and reliability of results. Instrumentation: Proficiency in operating and maintaining advanced analytical instruments used in the detection and analysis of extractables and leachables, including specialized chromatography and spectroscopy equipment.
	Statistics	Extensive knowledge and experience in: Understanding probability theory to assess likelihood and risk in drug development and quality control. Applying inferential statistics to draw conclusions from sample data about larger populations. Knowledge of various sampling methods to ensure representative data collection. Implementing statistical tools for monitoring and maintaining product quality. Analyzing and managing variability in manufacturing processes. Experience in designing and validating bioassays to evaluate drug potency. Validating analytical methods for accurate drug substance and product testing.	Data science and Machine learning concepts. Familiarity with regulatory and pharmacopeial standards.

		Understand and apply non-linear regression models for complex relationships. Familiarity with systematic approaches to enhance product quality and optimize processes.	
	Pharmaceutical Analysis Lifecycle & Data Science	Experience in validating, verifying, and transferring analytical methods. Ensure accuracy and reliability of procedures. Understand the entire lifecycle of analytical methods, from development to retirement. Apply statistical methods to analyze chemical data. Optimize processes and interpret results. Use statistical techniques to monitor performance. Assess measurement uncertainty and total analytical error. Familiarity with ISO guidelines for measurement uncertainty (MU) and total measurement uncertainty (TMU). Implement control charts for quality control. Apply DOE principles to optimize analytical methods. Systematically explore variables and interactions. Adapt methods for biologics (e.g., proteins, antibodies). Validate assays for potency, purity, and safety. Understand instrument qualification (IQ/OQ/PQ) processes. Ensure reliable instrument performance. Expertise in using volumetric equipment (pipettes, burettes) and balances. Precise measurements are critical. Understand measurement science and traceability. Ensure accurate and reliable measurements. Apply statistical methods for analyzing multiple variables. Optimize data interpretation. Assess and mitigate risks related to analytical methods. Ensure robust quality control processes.	Advanced Machine Learning

	Materials Physical Properties Characterization	Proficiency in analyzing crystal structures using microscopy techniques. Identify crystal forms and assess their impact on drug properties. Understand particle size distribution and morphology. Utilize image analysis software for accurate measurements. Apply optical methods to characterize particles and aggregates. Evaluate particle shape, size, and uniformity. Assess flow properties, viscosity, and consistency. Use rheometers and viscometers. Evaluate drug permeability across membranes. Understand factors affecting drug absorption. Study transitions (e.g., melting, crystallization) using thermal methods. Assess stability and polymorphism. Expertise in differential scanning calorimetry (DSC), thermogravimetric analysis (TGA), and hot-stage microscopy. Detect impurities and assess thermal behavior. Identify and quantify inorganic impurities (e.g., heavy metals). Ensure compliance with safety standards. Understand nanoscale drug delivery systems. Assess nanoparticle properties. Measure osmotic concentration. Ensure compatibility with physiological fluids. Determine drug solubility in various media. Optimize formulations. Evaluate the ability of suspensions to redisperse. Assess sedimentation and aggregation.	Color Instrumental Measurement Physical Stability (especially for Biological Products) Water Activity Instrument Qualification Reference Materials Environmentally friendly analytical technics. International Harmonization Regulatory GMP/GLP