What is Safety Pharmacology?
Safety pharmacology is a branch of pharmacology specializing in detecting and investigating potential undesirable pharmacodynamic effects of new chemical entities (NCEs) on physiological functions in relation to exposure in the therapeutic range and above.

Safety pharmacology studies are required to be completed prior to human exposure (i.e., Phase I clinical trials), and regulatory guidance is provided in ICH S7A and other documents.
Key Concepts of Safety Pharmacology
Primary organ systems (so-called core battery systems) are:
- Central Nervous System
- Cardiovascular System
- Respiratory System

Secondary organ systems of interest are:
- Gastrointestinal System
- Renal System
Key aims of safety pharmacology

The aims of nonclinical safety pharmacology evaluations are:

• To protect Phase I clinical trial volunteers from acute adverse effects of drugs

• To protect patients (including patients participating in Phase II and III clinical trials)

• To minimize risks of failure during drug development and post-marketing phases due to undesirable pharmacodynamic effects
The following key issues have to be considered within safety pharmacology:

• The detection of adverse effects liability (hazard identification)
• Investigation of the mechanism of effect (risk assessment)
• Mitigation strategies (risk management)
• Calculating a projected safety margin
• Implications for clinical safety monitoring
Pharmacology - the study of the action of xenobiotics, intended for therapeutic benefit, on physiological function

Toxicology - the study of the adverse effects of xenobiotics, intended or not intended for therapeutic benefit, on physiological function and structure

Adverse action(s) of a drug may or may not be related to pharmacological action.

EXAMPLES
Morphine  CNS - respiratory depression
Acetaminophen - Liver damage
Distinctions Between IND-enabling Toxicology & Safety Pharmacology

**Toxicology**
- Usually repeat dose studies
  - Effects of chronic/cumulative exposure up to a *maximum tolerated dose (MTD)*
- Major endpoints are structural changes to tissues collected at necropsy
  - Organ weights
  - Haematology
  - Biochemistry
  - Postmortem data: Histo
  - Morphologic & Histopathology
- Area Under the Concentration-time curve (AUC) driven

**Safety Pharmacology**
- Usually acute (single dose) studies
  - Effects of a single exposure to a dose that produces *moderate* adverse effects
- Endpoints are usually short term, reversible, functional effects recorded from *conscious* animals
  - Evaluate the onset, duration and magnitude of effects
- “C_{max}-driven” (C_{max} is the maximum serum concentration that a drug achieves in a specified compartment or test area of the body after the drug has been administrated and before the administration of a second dose)
Pharmacological Protocols Differ from Toxicological Protocols

- Pharmacology generally examines a single end point or a series of closely related endpoints in depth (e.g. cardiovascular, respiratory, CNS, renal, etc.)

- More concerned with function than structure. Functional changes can be acute and more severe (e.g. death from an arrhythmia) than histological changes with repeated dosing.

- Physiological changes can predict the risk for the risk for drug-induced morphological changes.
Types of Pharmacology

1. **Primary Pharmacology** - Effects of a substance in relation to its desired therapeutic target (Mechanism of Action; MOA).

2. **Secondary Pharmacology** - Identifying/understanding “off-target effects”. Effects of a substance not related to its desired therapeutic target (Formerly called “General Pharmacology”) can lead to a new therapeutic indication.
   - Rogaine® (minoxidil); Viagra® (sildenafil) (initial intended therapeutic effect- antihypertensive)

3. **Safety Pharmacology** - Investigates the potential undesirable pharmacodynamic effects of a substance on physiological functions in relation to exposure in the therapeutic range and above.
Drug Development Cycle

**PRE-CLINICAL STUDIES**

**Drug Discovery**
- Pharmacology
  - *Dose-Response*
  - *In vitro Studies*
  - *In vivo Studies (Efficacy)*
- Synthesis
- Lead Selection
  - Selectivity
  - Potency
  - *In vivo Pharmacology*
  - *PK Screening*

**Non- Clinical Development**
- Safety Pharmacology
  - *ICH S7A*
  - *ICH S7B*
- Toxicology
  - *Toleration*
  - Acute
  - Genetic
  - Chronic
  - Reproductive

**CLINICAL STUDIES**

**IND**
- Phase I
- Phase II
- Phase III
- Phase IV

**Therapeutic Drug**

**Regulatory Approval**

**NDA**

*(Pugsley et al., 2008: Br. J. Pharmacol.)*
Timing of Safety Pharmacology Studies In Relation to Clinical Development

1. Conducted prior to First Administration in Humans (FIH; IND application, “IND-enabling”)
2. During Clinical Development (Clinical Trials Phases 1-3)
3. Before Approval (NDA application)
4. Post-approval safety pharmacology investigations
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<td>NONCLINICAL EVALUATION FOR ANTICANCER PHARMACEUTICALS</td>
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ICH S7A and S7B

- Safety pharmacology studies are described in ICH guidances

- ICH S7A outlines the core battery studies and discusses the supplemental studies

- ICH S7B details the procedures for conducting an in vitro evaluation of delayed ventricular prolongation (QT interval prolongation)

- All safety pharmacology studies must be conducted in accordance with these guidances
Country-Specific Highlights: Canada

- Agency: Health Canada
- Website: http://www.hc-sc.gc.ca
- Member of the ICH. Adopts ICH guidance once routine administrative steps have been completed
  - In situations where an effective date cannot be established at the time of adoption and publication by Health Canada, an explanatory statement to this effect is included in the covering notice and the title page of the guidance
Country-Specific Highlights: Japan

- Agency: Pharmaceuticals and Medical Devices Agency
- Website: http://www.pmda.go.jp/english/
- Member of the ICH.
- Has specific guidelines for vaccine development
  - Guidelines for nonclinical studies of prophylactic vaccines for infectious diseases (2010)
    - Safety pharmacology studies are required
    - Toxicity testing of novel vaccine excipients and adjuvants are required
Country-Specific Highlights: USA

- **Agency:** Food and Drug Administration
- **Website:** [http://www.fda.gov](http://www.fda.gov)
- **Member of the ICH.**
- **Center for Drug Evaluation and Research (CDER)** regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. **Center for Biologics Evaluation and Research (CBER)** regulates biological products for human use.
- **Has specific guidelines for nonclinical study types that are not covered by ICH or WHO** (e.g. vaccine reproductive toxicology studies)
Country-Specific Highlights: Australia

• Agency: Therapeutic Goods Administration (TGA)
• Website: http://www.tga.gov.au/
• Generally follows ICH and WHO
• Genetic toxicology testing required for enantiomers
  • Impurities in Drug Substances and Drug Products
Country-Specific Highlights: Brazil

- Agency: Brazilian Health Surveillance Agency, ANVISA
- Website: http://portal.anvisa.gov.br/wps/portal/anvisa-ingles
- Generally follows ICH and WHO
- Anvisa is responsible for drug registration and licenses to pharmaceutical laboratories and companies inside. The agency is also responsible for establishing regulations applicable to clinical trials and drug pricing, which is carried out by the Chamber of Drug Market Regulation.
Country-Specific Highlights: China

- Agency: China Food and Drug Administration
- Website: http://eng.sfda.gov.cn/WS03/CL0755/
- Has specific guidelines for drug/vaccine development
  - Manufacturing site change requirements (2013)
  - China Drug Registration regulation and Annex 3 (Registration Categories and Application Information Items Requirements of Biological Products) requires that “Quality certificate of the animal used for production, research and test” be provided for Preventive Biological Products (vaccines).
Country-Specific Highlights: France

- Agency: French National Agency for Medicines and Health Products Safety (ANSM)
- Website: http://ansm.sante.fr/Mediatheque/Publications/Information-in-English
- Follows ICH and WHO
- Agence nationale de sécurité du médicament et des produits de santé (ANSM) was created on 29 December 2011. Under the supervision of the Ministry of Health, the ANSM took over the tasks of the previous AFSSAPS.
Country-Specific Highlights: Germany

- Agencies: The Federal Institute for Drugs and Medical Devices (BfArM) and the Paul-Ehrlich-Institut (PEI)
- Websites: http://www.bfarm.de/EN/Home
  - http://www.pei.de/EN/home/
- Follows ICH and WHO
- BfArM is involved in the tasks of licensing, improving the safety of medicinal products, detecting and evaluating the risks of medical devices, and monitoring the legal traffic in narcotic drugs. The Paul-Ehrlich-Institute activities promote the quality, efficacy and safety of biological medicinal products.
Country-Specific Highlights: India

- Agency: Central Drugs Standard Control Organization
- Website: http://www.cdsco.nic.in/
- Has specific guidelines for drug/vaccine development
  - Drugs and Cosmetics (IIND Amendment) Rules “Schedule Y” (2005)
    - Treats vaccine like a small molecule and requires studies in two species, and requires both single-dose and repeat-dose toxicity studies
Country-Specific Highlights: South Korea

- Agency: Ministry of Food and Drug Safety
- Website: http://www.mfds.go.kr/eng/index.do
- Follows ICH and WHO
- The Ministry of Food and Drug Safety (MFDS) formerly known as the Korea Food & Drug Administration (KFDA) is responsible for ensuring the safety and efficiency of foods, pharmaceuticals, medical devices and cosmetics as well as supporting the development of the food and pharmaceutical industries.
Country-Specific Highlights: Russia

- Agency: Federal Service for Control of Healthcare and Social Development in the Russian Federation (Roszdravnadzor)
- Website: [http://www.roszdravnadzor.ru/](http://www.roszdravnadzor.ru/)
  - Roszdravnadzor oversees all domestic and imported drugs and medical devices in Russia. It governs and controls the registration procedure, approves or rejects applications for state registration, and works to ensure clinical safety and efficacy of drugs and medical devices.
- Generally follows ICH and WHO, however has some unique features (e.g. requests carcinogenicity study data earlier in development when compared with other regions)
Country-Specific Highlights: UK

- Agency: Medicines and Healthcare Products Regulatory Agency (MHRA)
- Website: http://www.mhra.gov.uk/
- Follows ICH and WHO
- MHRA is a center of the Medicines and Healthcare Products Regulatory Agency which also includes the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD).
Regulatory Conclusions

1. There is NOT MUCH DIFFERENCE between the 3 regions (Canada, Japan & USA) that all follow ICH-S7A/7B

2. Use of “Global Dossier” (i.e., same nonclinical package in ALL regions) – EXCEPT in Japan – where there are some additional nonclinical requirements depending on the drug, product, therapeutic area and route of administration(s).

3. Existence of “case-by-case” (more particularly in Japan/PMDA) where PMDA tends to ask for more than other regions (e.g., for vaccines & biologics: typically need to provide stand-alone Safety Pharmacology studies), otherwise lengthy scientific justifications to explain why they were not performed?...

4. Importantly, Vaccines are NOT covered under ICH-S7A/S7B but:
   i. Japan is still requiring Nonclinical Safety Pharmacology studies (PDMA Vaccine licensure);
   while;
   ii. No other regions require SP package for vaccines unless there is a cause for concern!

New paradigm shift in cardiac toxicity evaluation in Early and Late Drug Development phases via new Working Groups/Consortia involving academicians, regulators and industry key leaders that have driven new initiatives (CiPA) to propose and refine for example the ICH/E14 then, ICH-S7b that should contribute to a BETTER understanding of the pro-arrhythmic cardiac risk liability of drugs, and therefore, ensure a better patient safety.

AND...

You must be in ............ COMPLIANCE
Dose Levels

- Safety pharmacology studies should be designed to define the dose-response relationship of the effect observed.
- Doses should include and exceed the primary pharmacodynamic or therapeutic range. In the absence of an adverse effect on the safety pharmacology parameter(s) evaluated in the study, the highest tested dose should be a dose that produces moderate adverse effects in other studies of similar route and duration.
Study Design

- Study Group Size: sufficient to allow meaningful scientific interpretation of the data generated.
- Appropriate negative and positive control groups should be included in the experimental design.
  - In well-characterized in vivo test systems, positive controls may not be necessary.
  - The exclusion of controls from studies should be justified.
- In general, the expected clinical route of administration should be used when feasible. Assessment of effects by more than one route may be appropriate if the test substance is intended for clinical use by more than one route of administration, or where there are observed or anticipated significant qualitative and quantitative differences in systemic or local exposure.

Latin Square Design
Good Laboratory Practice (GLP)

- Safety pharmacology core battery studies should be conducted in compliance with GLP.
- Follow-up and supplemental studies should be conducted in compliance with GLP to the greatest extent feasible.
- Primary pharmacodynamic studies do not need to be conducted in compliance with GLP.
Core Battery

Central Nervous System (CNS): Rats (Monkey)

- Irwin screen (including body temperature)/Functional Observational Battery (FOB)
- Pro-convulsive activity
- Motor activity

Cardiovascular: Dog, Monkey (Guinea Pig)

- Blood pressure, heart rate, ECG in vitro and/or ex vivo methods including electrophysiological techniques

Respiratory: Rat, Dog, Monkey

- Respiratory rate and tidal volume or hemoglobin oxygen saturation
Follow-Up Studies

Central Nervous System (CNS):
• Behavioral pharmacology, learning and memory, ligand-specific binding, neurochemistry, visual, auditory and/or electrophysiology examinations, pro-convulsion, abuse ability.

Cardiovascular:
• Cardiac output, ventricular contractility, vascular resistance, effects of endogenously released and/or exogenously administered neurotransmitters on cardiovascular response.

Respiratory:
• Airway resistance, compliance, pulmonary arterial pressure, blood gases, blood pH
Supplemental Studies

Renal/Urinary System:
- Urine analysis including data for volume, specific gravity, osmolality, pH, fluid/electrolyte balance, proteins, cytology and blood chemistry (such as blood urea nitrogen, creatinine and plasma proteins)

Autonomic Nervous System:
- Binding to receptors relevant for the autonomic nervous system, agonist and antagonist responses in vivo or in vitro, direct stimulation of autonomic nerve and measurement of cardiovascular responses, baroreflex testing and heart rate variability

Gastrointestinal System:
- Gastric secretion, gastrointestinal injury potential, bile secretion, transit time in vivo, ileal contraction in vitro, gastric pH measurement and pooling

Other Organ Systems:
- Effects of organ systems not investigated elsewhere. For example, dependency potential or skeletal muscle, immune and endocrine functions
Careers in Safety Pharmacology
Who are safety pharmacologists?
- Safety pharmacologists are individuals who work in various industries to further the discovery, development and safe use of biologically active chemical entities by the identification, monitoring and characterization of potentially undesirable pharmacodynamic activities in nonclinical studies. They investigate the potential undesirable pharmacodynamic effects of a substance on physiological functions in relation to exposure in the therapeutic range and above.

What do they do?
- Academic institute
- Regulatory agency
- Contract research organization
- Pharmaceutical industry
- Consultant

Areas of specialization
- Often specialization is seen in one or more areas of the Core battery (see slide 31)

Degrees/Training/Certifications to obtain
- BS, MS, BSc, Msci, PhD, DSP

Salary – see the most recent SPS Salary Survey
Careers in Safety Pharmacology

- Safety pharmacologists come from a variety of disciplines:
  - Neuroscience
  - Cardiovascular
  - Toxicology
  - Biochemistry
  - Pharmacology
  - Veterinary medicine...

- There are several universities globally that offer degrees and/or programs in safety pharmacology
  - The Ohio State University (USA), Michigan State University (USA), University of Cincinnati (USA), University of Bradford (UK) and more..

- Safety pharmacology is often its own department within a Pharmaceutical company but can also be part of another department such as Toxicology or PKDM
What do Safety Pharmacologists do?

- Chemistry (SAR)
- Pharmacology
- Drug Class
- Toxicology

Safety Pharmacology ‘Core Battery’ Studies

- CNS
  - Motor Activity
  - Behavior
  - Coordination
  - Sensory/Motor Reflexes
  - Body Temperature

- Cardiovascular
  - BP & Heart Rate
  - ECG
  - Repolarization (APD)
  - hERG (I_{Ks}) assay
  - Conduction

- Respiratory
  - Respiratory Rate
  - Tidal Volume
  - O_2 Saturation

Pharmacodynamics
Pharmacokinetics
Safety Studies
Drug Interactions
Who are Safety Pharmacologists?

A. Geographic location
- North America East Coast: 39
- North America West Coast: 11
- Central or South America: 30
- Europe: 18
- Asia: 2
- Other (please specify): 2

N=129

B. Company size
- Less than 10 employees: 13
- 10-100 employees: 27
- 100-1000 employees: 10
- 1000-10000 employees: 10
- More than 10000 employees: 40

N=129

C. Age category
- Less than 30 years: 33
- 31-39 yrs: 23
- 40-49 yrs: 11
- 50-59 yrs: 4
- 60-69 yrs: 2
- (>70 yrs): 1

N=128

D. Number of employees supervised/managed
- No direct management responsibility: 53
- Less than 5 employees: 18
- 6-20 employees: 21
- 20-200 employees: 21
- 200-1000 employees: 8
- More than 1000 employees: 1
- Other (please specify): 4

N=122
Area of Specialization

- Ion channels/in vitro assays
- CV safety pharm
- CNS safety pharmacology
- Respiratory SP
- GLP compliant studies
- Discovery
- Drug abuse liability
- PK
- Biologics
- NCE
- Regulatory filing/submissions
- CMC/Formulations
- Pathology
- Toxicology
- Other (please specify)

N=121
The **Diplomate in Safety Pharmacology certification exam** consists primarily of:

- Material pertinent to the conduct of SP core battery studies
  - Cardiovascular, respiratory and central nervous systems
  - Supplemental SP studies (i.e., renal/urinary, gastrointestinal, immunology, and hematology)
  - Regulatory Guidelines (ICH Guidelines)
  - Relevant cross-functional knowledge (e.g., physiology, pharmacology, toxicology, biochemistry, pathology, pharmacokinetics, dosing formulation, analytical methods, study design and statistics)

- Maintenance of the DSP certification results from the accrual of credits which are gained from a range of educational and scientific contributions

- Eligibility: A combination of at least a BSc in Science + 2 years relevant professional SP experience (+ 1 poster presentation on a SP topic as first author at a recognized major scientific meeting).
Market for Safety Pharmacologists

- Toxicologist
- Pharmacologist
- Safety Pharmacologist
- Physiologist
- Toxicologist/Pharmacologist
- Other (please specify)

N=122
Safety Pharmacology Society

Professional Experience of Safety Pharmacologists

- **Less than 2 years**: 5
- **2-4 years**: 3
- **4-6 years**: 7
- **6-8 years**: 14
- **8-12 years**: 11
- **12-16 years**: 17
- **16-20 years**: 17
- **20-25 years**: 22
- **25-30 years**: *
- **More than 30 years**: *

N=126
Safety Pharmacology Society
Salary of Safety Pharmacologists

N=120

- 14 salaries in the $220,001-$250,000 range
- 14 salaries in the $250,001-$300,000 range
- 14 salaries in the $300,001-$350,000 range
- 13 salaries in the $140,001-$160,000 range
- 11 salaries in the $60,001-$80,000 range
- 8 salaries in the $80,001-$100,000 range
- 6 salaries in the $100,001-$120,000 range
- 5 salaries in the $40,000-$60,000 range
- 3 salaries in the $120,001-$140,000 range
- 3 salaries in the $180,001-$200,000 range
- 3 salaries in the $200,001-$220,000 range
- 2 salaries in the $350,001-$400,000 range
- 1 salary in the $160,001-$180,000 range
- 1 salary in the $200,001-$220,000 range
- 1 salary in the $350,001-$400,000 range

55% of the salaries fall into the $60,001-$80,000 range.
Salary of Safety Pharmacologists
Incentive Income of Safety Pharmacologists

- Less than $5,000: 38
- $5,000-$10,000: 3
- $10,001-$15,000: 5
- $15,001-$20,000: 9
- $20,001-$30,000: 11
- $30,001-$40,000: 3
- $40,001-$50,000: 2
- $60,001-$70,000: 3
- $70,001-$80,000: 2
- $80,001-$100,000: 6
- $100,001-$120,000: 9
- $120,001-$150,000: 3
- $150,001-$200,000: 2
- More than $200,000: 2

N=118
Conduct studies (CNS, Respiratory and CV) to characterize the confidence by which biologically active new chemical entities (NCE) may be anticipated as safe.

Non-clinical safety pharmacology studies aim to detect and characterize potentially undesirable pharmacodynamic activities using an array of in silico, in vitro and in vivo animal models.

Safety Pharmacologists have expansive backgrounds with a good understanding of core battery assays used to characterize the safety profile of a NCE/Biologic.

Safety Pharmacologists advance the science.
About the Safety Pharmacology Society
About the Safety Pharmacology Society (SPS)

Mission
Safety Pharmacology Society is a nonprofit organization that promotes knowledge, development, application, and training in Safety Pharmacology—a distinct scientific discipline that integrates the best practices of pharmacology, physiology and toxicology. The objective of Safety Pharmacology studies is to further the discovery, development and safe use of biologically active chemical entities by the identification, monitoring and characterization of potentially undesirable pharmacodynamic activities in nonclinical studies. The Safety Pharmacology Society also supports the human safety of drugs and biologicals by fostering scientific research, education, and dissemination of scientific information through meetings and other scientific interactions.

Purpose: Safety pharmacology leaders providing guidance and answers to critical questions that matter to patients, regulators, and scientists.
About the Safety Pharmacology Society (SPS)

Vision

The Society’s vision is to lead the global safety pharmacology community in the development and safe medical use of biologically active molecular entities by bridging across disciplines to predict, identify, characterize, monitor and mitigate potentially undesirable pharmacodynamic activities in nonclinical studies and guiding their translation into clinical trials and beyond, to benefit all patients.
About the Safety Pharmacology Society (SPS)

- Founded in 2000
- 500 Members
- Annual Meeting every year (rotates between North America and Europe)
- 12+ Educational webinars/year
- 2+ Regional Meetings/year
- Award Opportunities
- Access to vendor products and new technologies
- Speaking and Poster presentation opportunities
- Job Bank and Career resources
- Networking and collaborative opportunities

www.safetypharmacology.org
The Safety Pharmacology Society has established a process for certification which evaluates and documents competency in the field of safety pharmacology. There is a need from the industry, and regulators worldwide for a certification process to confirm expertise and identify quality standards for professionals involved in the practice of safety pharmacology.

Candidates for certification must achieve a passing grade on a 200 question (multiple choice) exam. Presently the exam is given once a year in conjunction with the SPS Annual Meeting.

The exam questions cover regulatory, safety pharmacology systems and cross-discipline knowledge.

Full eligibility and details can be found on the website.
In summary, safety pharmacology is a discipline that plays an important role in protecting human volunteers and patients from a new compound’s potential for undesirable pharmacodynamic effects.

Safety pharmacology studies evaluate nervous system, cardiovascular and respiratory function over a range of doses in the therapeutic range and above that do not cause overt toxicity.

Safety pharmacology is a diverse and exciting field that offers careers in a number of different areas such as academia, industry and regulatory agencies.