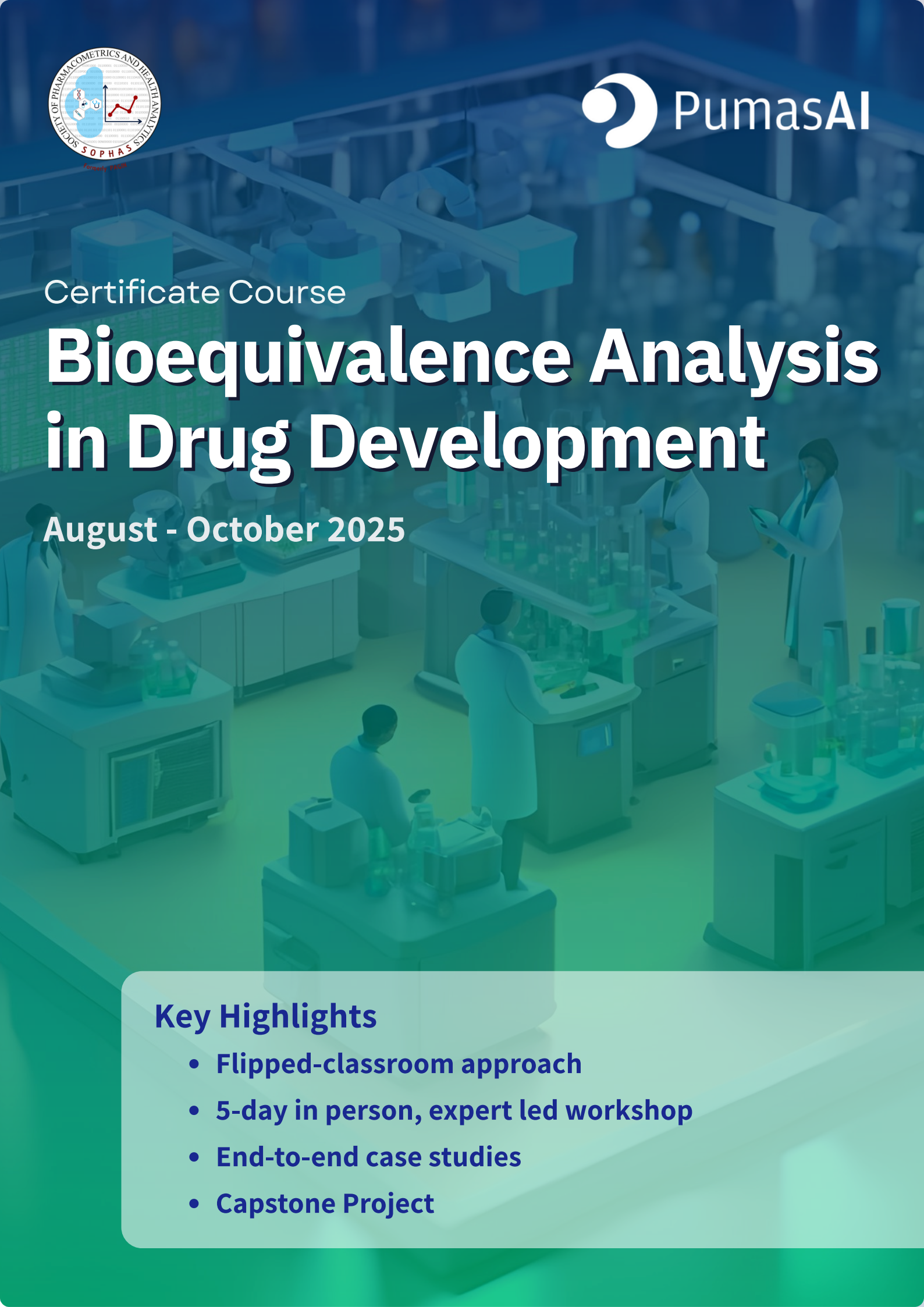


Certificate Course

Bioequivalence Analysis in Drug Development

August - October 2025

Key Highlights

- Flipped-classroom approach
- 5-day in person, expert led workshop
- End-to-end case studies
- Capstone Project

Weekly Effort
4 to 6 hours/week

Learning Mode
Virtual + 5-day in-person workshop

Duration
3 months

Eligibility
Students, Graduates & above

Certification
Certificate of Completion/ Attendance

Learning Experience

Pre-recorded lectures, guided materials
Flexible learning that works with your schedule

Mentors with global impact
Learn from the best academic and industry experts

5 days immersive in-person workshop
Blend theory with hands-on, project based leaning experience

Licensed softwares & tools
Access to state of the art, industry standard softwares and tools

Phase I

Structured Virtual Learning

Aug 1– Aug 30, 2025

- Self-Paced
- Access to lectures, materials, softwares & tools
- Assignments & exercises

Phase II

Project-Based Learning

Aug 31– Sep 4, 2025
Location: PSG IMSR, Coimbatore

- In person workshop
- In-depth training
- Capstone project
- Case studies

Submission & Certification

Second week of Oct 2025

- Project submission
- Final assessment
- Certification (Completion/attendance)

Phase III

Frequently Asked Questions

Is there a qualifying mark to receive the final certification in this course?
Yes. To successfully complete the course and receive a certificate of completion, participants must achieve a minimum score of 70% in all required assignments. A certificate of attendance will be provided to the participants who complete phase one and attend the in-person workshop.

What if I miss an assignment deadline? Can I submit it later?
Assignments not submitted by the due date will be considered late. Late submissions are accepted until one week after the course end date. Please note that feedback will not be provided for late assignments.

Will there be dedicated doubt-clearing sessions?
Yes. Weekly office hours will be conducted throughout the duration of the course to address participants' questions.

How long will I have access to the learning materials?
You will have access to the online platform, including videos and all course materials, for 12 months from the course start date. Access is limited to registered participants as per the terms of use.

What software tools will I learn?
Participants will receive hands-on training in Pumas and PumasCP, advance tools for pharmacometrics modeling and clinical trial simulations widely used in bioequivalence studies.

How long will I have access to the licensed software after the course ends?
Students: Free access (academic license).
Industry participants: A 6-month evaluation desktop license.

What is the teaching methodology?
We follow a Flipped Classroom approach:
Phase 1: Self-paced virtual learning of theoretical concepts.
Phase 2: Hands-on, collaborative in-person workshop to apply your knowledge.

Do I need prior experience in pharmacometrics or advanced statistics?
Prior exposure to basic statistics is helpful but not required. The course is designed to build your knowledge from foundational concepts to advanced applications, making it accessible to participants without prior pharmacometrics experience.

What will I receive upon completing the course?
Participants will be awarded:
Certificate of Attendance – for completing Phase 1 and attending the workshop, Phase 2.
Certificate of Completion – for those who submit the final project and meet the performance criteria.
Both certificates demonstrate your skills in designing and analyzing bioequivalence studies.

Can international participants apply?
Yes. International participants are welcome. Please note that the default country in the registration form is India—this can be updated during registration. The in-person workshop will be held in India. For more information write to us at connect@sophas.net.

Will I receive support after the course if I have further questions?
Yes. Participants will have access to discussion forums to engage with instructors and peers even after the course ends.

What if I want to attend this course but cannot do so in person in India?
No problem! Please write to us at connect@sophas.net with your request or drop a message on LinkedIn. We'll be happy to explore alternative options with you.

Course Highlights

10+
Recorded video lectures and curated readings for foundational learning

1
Capstone project simulating a full bioequivalence study

10+
Hands-on assignments and problem sets to reinforce key statistical concepts

Advanced software tools: Pumas & PumasCP for modern BE modeling

10+
Case studies in bioequivalence analysis

Led by global experts from Pumas-AI

5
Days of intensive in-person workshop with expert-led sessions

Training aligned with FDA and global regulatory expectations

3
Phases: Virtual learning, in-person workshop, and project submission

Be part of a global learning community advancing bioequivalence science in collaboration with PumasAI and SOPHAS

Course Modules

Unit 1

What is a bioequivalence study?

Unit 2

On log transformed data, geometric means, and the log-normal distribution

Unit 3

A basic example using parallel design, the TOST idea

Unit 4

Different experimental designs

Unit 5

The basic linear model for average bioequivalence

Unit 6

ABE using Pumas and PumasCP

Unit 7

Understanding marginal means

Unit 8

Basics of power analysis

Unit 9

Nonparameteric test

Unit 10

Details of linear and mixed models

Unit 11

Intro to Narrow Therapeutic Index Drugs (NTIDs)

Unit 12

Reference scaling with FDA - part I

Unit 13

Reference scaling with FDA - part II

Unit 14

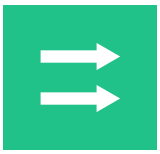
On Type III p-values

Unit 15

Conclusion and other Pumas BE features

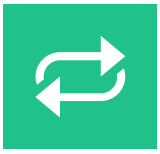
Case Studies

BE study design
Key considerations for designing a robust and compliant bioequivalence trial



Parallel
Evaluating bioequivalence when subjects receive only one formulation per treatment period

Cross-over
A common design where subjects receive both test and reference treatments in alternating periods



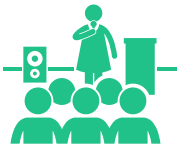
Replicate and Partial replicate cross overs
Special crossover designs to estimate within-subject variability and scale acceptance limits.

Replicate reference
A design focusing on repeated reference treatments to assess reference variability and scaling criteria

Multiple formulation
Comparing multiple test formulations to a common reference in one integrated study design

Virtual BE for LAI
Using simulation and modeling to evaluate bioequivalence of long-acting injectables (LAIs)

Learning Journey



Orientation Week

The first week is an orientation to introduce you to fellow participants and familiarize you with the learning platform and tools.

Self-paced, Flexible Online Learning

Phase 1: Structured Virtual Learning, 1 month (1 Aug to 31 Aug 2025)
Learn online through recorded lectures, guided materials, and licensed tools, with a flexible commitment of 4–6 hours/week.

Office Hour Sessions

Attend weekly online sessions to clear doubts and review key concepts. Assignments will be graded by the grading team.

Weekly Goals

As you begin the course, focus on weekly goals like completing assignments before their deadlines.

Project-Based Workshop (In-Person)

Phase 2: Project-Based Learning, 5 days In-person at PSG IMSR, Coimbatore
Apply your knowledge through a hands-on capstone featuring real-world datasets, Pumas software, Q/A sessions and feedback.

Final Submission & Certification

Phase 3: Submission & Certification
Submit your assignments and projects and receive appropriate certificates.
Certificate of Attendance: For completing online and in-person sessions
Certificate of Completion: For successful project submission

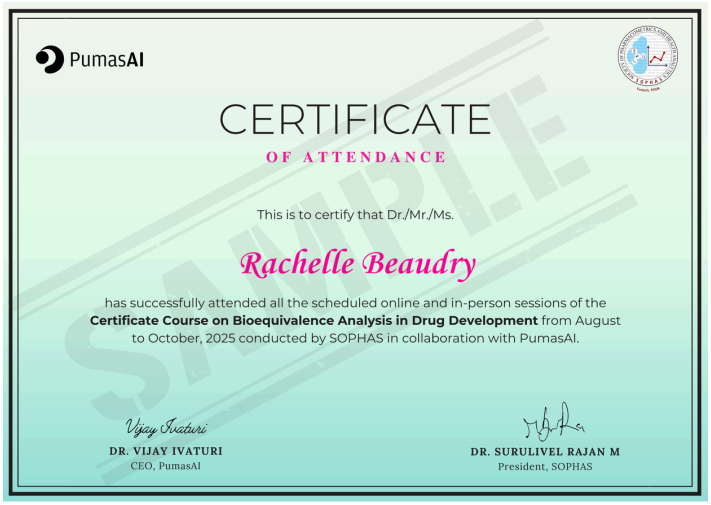
Course Certificate

Based on participation and performance, participants will be awarded one of the following:

- Certificate of Attendance: For those who complete the virtual learning and attend the in-person workshop.

- Certificate of Completion: For those who submit the capstone project and meet performance criteria.

These certificates formally acknowledge the participant's proficiency in designing, analyzing, and interpreting bioequivalence studies to support data-driven decision-making in drug development.



Who Is This Course For

This certificate program is designed for individuals who are keen to build practical skills in bioequivalence analysis and contribute meaningfully to drug development. It is ideally suited for:

Early-career professionals in the pharmaceutical, biotechnology, and contract research industries who want to strengthen their understanding of bioequivalence studies and their regulatory applications.

Researchers and scientists involved in pharmacokinetics, clinical pharmacology, and biostatistics who seek to apply statistical methods to the design and analysis of bioequivalence studies.

Graduate and postgraduate students (PharmD, MPharm, PhD, MSc, etc.) in pharmacy, pharmaceutical sciences, biostatistics, clinical research, or related fields who want to gain hands-on experience with modern software tools and study designs.

Regulatory affairs professionals who wish to deepen their insight into bioequivalence requirements and virtual bioequivalence approaches relevant to global regulatory submissions.

Clinical trial managers and coordinators looking to enhance their ability to design, oversee, and interpret bioequivalence studies within development programs.

Educators and academic researchers interested in updating their knowledge base and integrating practical bioequivalence concepts into teaching or research programs.

Anyone aiming to transition into or specialize in bioequivalence analysis within the broader field of drug development, including professionals in allied domains such as medical writing, data management, or health economics.

We welcome participants from India and abroad, offering a blend of virtual learning and hands-on experience that can add value at any stage of a professional or academic journey.

Why This Course?

Develop a solid foundation in bioequivalence (BE) study design and regulatory principles.

Gain hands-on experience using Pumas and PumasCP to model and analyze BE data.

Learn to plan power and sample size for successful BE studies.

Apply statistical methods to analyze, interpret, and report BE trial results.

Understand latest FDA and global guidelines for BE and bioavailability testing.

Explore advanced concepts like virtual bioequivalence and trial simulations.

Strengthen your ability to make informed, data-driven decisions in drug development.

Engage with industry experts and peers to exchange knowledge and practical insights throughout the programme.

Course Instructors

DR. YONI NAZARATHY

Expert Statistical Consultant, PumasAI

Dr. Yoni is a machine learning, statistics, and data science expert. Outside of Accumulation Point, he is an Associate Professor at the School of Mathematics and Physics in The University of Queensland. He has vast experience and a proven track record in connecting theory and practice to bridge the gap between research and innovative real world solutions. Beyond Accumulation Point consulting projects, some of his notable recent creations include, the Mathematical Engineering of Deep Learning book, a book on Statistics with Julia, and leadership of the Safe Blues Project.

DR. VIJAY IVATURI

CEO, PumasAI

Dr. Ivaturi is a distinguished pharmacometrician, academic, and biotech leader. He bridges advanced research spanning PK/PD modeling, precision dosing, and regulatory science, with entrepreneurship. He is the Co-Founder and CEO of PumasAI, President of the International Society of Pharmacometrics (ISoP), and holds the position of Endowed Chair at the Center for Pharmacometrics, Manipal. Dr. Ivaturi earned his B.Pharm from MAHE, Manipal, followed by an M.S. in Pharmaceutics from St. John's University, and a Ph.D. in Clinical Pharmacology and Pharmacometrics from the University of Minnesota. He also completed a postdoctoral fellowship in Pharmacometrics at Uppsala University, Sweden. His work continues to advance model-informed drug development (MIDD) through cutting-edge science, education, and global collaboration.

DR. KRISHNA DEVARAKONDA

Visiting & Adjunct Faculty, Thomas J. Long School of Pharmacy, University of the Pacific

Dr. Devarakonda brings over 30 years of experience, combined with nearly two decades of leadership in clinical research and development in the U.S. pharmaceutical industry. A recognized expert in Clinical Pharmacology, his work has advanced therapeutic areas such as cancer biology, metabolic diseases, acute pain, and opioids. His deep expertise extends across PK/PD, cell culture, and drug formulation sciences backed by a strong track record of bridging lab research with real-world clinical applications. In addition to his industry contributions, Dr. Devarakonda is committed to education and mentorship as Visiting & Adjunct Professor at the University of the Pacific's Thomas J. Long School of Pharmacy, where he continues to guide and inspire the next generation of scientists and clinical researchers.

Hands-on Learning with Pumas

Pumas combines cutting-edge science, advanced artificial intelligence, and powerful computing to revolutionize and streamline the drug development process.

Pumas

Designed to deliver unparalleled precision, speed, and adaptability, Pumas stands out as the fastest and most advanced tool for comprehensive drug development analysis. It integrates state-of-the-art algorithms and superior solver technology to handle complex pharmacokinetic and pharmacodynamic models, setting a new gold standard in the industry.

Pumas stands out with its unmatched technical capabilities and continuous innovation, driving the pace of innovation in pharmacometrics. Trusted by leading pharmaceutical companies and regulatory bodies worldwide, Pumas ensures that your drug development process is efficient, accurate, and regulatory-ready.

REGULATORY-READY CONFIDENCE

UNPARALLELED PRECISION

ONE SOLUTION FOR EVERY QUESTION

LIGHTNING-FAST PERFORMANCE

- Non-Compartmental Analysis
- Dose Proportionality & Bioequivalence
- Nonlinear Mixed-Effects Modeling
- Physiologically Based PharmacoKinetics
- Quantitative Systems Pharmacology
- Clinical Trial Simulations
- Bayesian Estimation

Hands-on Learning with PumasCP

PumasCP

PumasCP, a graphical user interface tool, transforms the way your Non-Compartmental Analysis (NCA), Bioequivalence (BE) and Toxicokinetic (TK) analyses are managed. With seamless automation, flexible customization, and built-in compliance, PumasCP empowers scientists to streamline workflows, reduce manual burden, and deliver high-quality insights faster and smarter.

With a focus on efficiency and designed to grow with your team, PumasCP helps users spend less time navigating and more time uncovering insights, maximizing ROI and enabling breakthroughs.

Course Details

Course Start Date: August 1, 2025

Course Duration: 3 months

Couse Fee:
*Inclusive of GST

Category	Full Course Fee		
	INR	USD	EUR
Students	₹6,000	$80	€60
Academics	₹7,000	$90	€70
Industry	₹20,000	$240	€200

Workshop Location & Dates:
PSG IMSR, Coimbatore
Sun, 31 Aug – Thu, 4 Sep 2025

REGISTER NOW

About Us

PumasAI

PumasAI is a global healthcare intelligence company with a vision to accelerate precision healthcare for patients. Proprietary software developed by the company includes the Pumas suite of products, an integrated modeling and simulation platform designed to multiply productivity across the drug development lifecycle, and Lyv, a clinical decision support system that leverages patient history and targeted medical data for personalized healthcare delivery. Scientists at PumasAI provide consulting with leading pharmaceutical innovators in clinical pharmacology, model-informed drug development, pharmacometrics, front-end applications, and more.

AskPumas Pumas DeepPumas PumasCP Scientific & Strategic Consulting Services

About Us

Society of Pharmacometrics & Health Analytics

Professional society dedicated specifically to quantitative sciences within clinical pharmacology and broadly in health data analysis

This society has its roots in the “Population Approach Group in India – PAGIN” started in the year 2008 and has successfully propagating pharmacometrics in India ever since. PAGIN is known around the world and recognized by other pharmacometric societies for its annual pharmacometric workshops. The SOPHAS society is working with an expanded mandate including health care data analytics along with our core focus on pharmacometrics in drug development and clinical applications.

About Us

PSG INSTITUTE OF MEDICAL SCIENCES & RESEARCH

PSG Institute of Medical Sciences and Research

PSG is a 92 years legacy in education and industry in our country. Testimony to the fact is the alumni spread across the nation, so also across the length and breadth of the globe. The PSG group of institutions specializes in providing comprehensive learning in a variety of academic fields' right from Arts and Sciences to Engineering and from Medicine to Management. With nearly 1000 strong teaching staff and up to 16000 students under its wing, PSG has been constantly breaking barriers in education.

Be Future Ready: Join the Bioequivalence Analysis in Drug Development course now

REGISTER NOW

For queries and any other information, please get in touch with us at **connect@sophas.net** or drop a message on **LinkedIn**

Explore the 32 Weeks **Certificate Course on AIDD (Artificial Intelligence in Drug Development)** by PumasAI and SOPHAS

CERTIFICATE COURSE ON AIDD

Organized by

PumasAI

Society of Pharmacometrics and Health Analytics (SOPHAS)

In collaboration with

PSG Institute of Medical Sciences and Research