SINCE 2008

# Aurous HealthCare

## Research & Development India Pvt. Ltd.

***The Pioneer CRO with Focus on Clinical Research...***



# SERVICE PORTFOLIO

- Clinical Trial Planning & Management
- CDSCO Sugam Submission & Approvals
- CDSCO MedDev Submission & Approvals
- Clinical Trials : Concept to Customer
- Proof of Concept Studies
- AYUSH Clinical Trials
- End to End Clinical Trial Services
- Site Management Activities
- Medical Writing
- Regulatory Strategy & Consulting
- Regulatory Submissions : PSUR, PSMF
- Safety Reporting & Pharmacovigilance

# CONCEPT TO CONSUMER

- Scientific Validation of Safety & Efficacy.
- Proven Product Claims.
- Stand out amongst competitors.
- Build Customer confidence.
- Improved marketing resources & data.
- Regulatory compliance .
- Global reach for authenticated claims.
- Scientifically designed assessments.
- Improved product placement.
- Publish in peer reviewed journals.

Aurous HealthCare (AHC) is an independent ISO 9001:2015 certified organisation with focus on Clinical Research.

Established in mid-2008 by **Dr.VT.Sriraam MBBS MD (Pharmacology).** AHC was built to provide research services in strategic and innovate ways.

**Our specialty is the Single Window Approach to Product Research!** Our experience in clinical trials extends to Vaccines, Medical Devices, Herbal Medicines and Cosmetics, Ayurveda and Siddha medicines, Nutraceuticals & Cosmeceuticals.

AHC was established with the intent of bridging the gap as a one stop solution for anyone looking to get their product validated for its safety and efficacy through clinical studies.
We are with you, every step of the way, from conceptualisation of the study design, documentation, conduct of the clinical study, statistical analysis, reporting and all regulatory approvals & registrations.

## CLINICAL TRIAL CALIBRE

- Vaccines
- Medical Devices
- FDC, Chemical Entities
- Drug Repositioning
- Ayurveda : Medicines, Cosmetics, Supplements
- Siddha : Medicines, Cosmetics
- Nutraceuticals
- Nutritional Supplements
- Cosmeceuticals
- Herbaceuticals
- Post Marketing Surveillance
- Post Marketing Clinical Follow Up

## THERAPEUTIC EXPERTISE

- Dermatology
- Orthopaedics
- Vaccines
- Dlabetology
- Urology
- Geriatrics
- Cardiology
- Opthalmology
- Gynaecology
- Infertility
- Metabolic Diseases
- Food & Nutrition
- Central Nervous System
- Alimentary System
- Immunology
- Psychiatry
- Gastroenterology

# AUROUS HEALTHCARE

Experience & Expertise




WWW.AUROUSHEALTHCARE.COM

An alumnus from Govt. Stanley Medical College & Madras Medical College, **Dr.VT.Sriraam** has 20+ years of experience as a doctor and over 15+ years in the field of clinical & medical research.

Dr.Sriraam is the youngest first generation medical entrepreneur of India in the field of medical research & healthcare successfully taking Aurous HealthCare CRO forward towards its 16th year.

Dr.Sriraam transformed his passion for medical research into providing research solutions by founding **Aurous HealthCare CRO** in 2008. As the Medical Director of AHC, Dr.Sriraam has been providing expert research solutions to clients from India and across the globe - Japan, United Kingdom, Singapore, Malaysia.

Dr.Sriraam has been recognised with National Award - "Indian Leadership Award for Healthcare Excellent", for his contributions in the field of medical research.

*An astute medical entreprenuer, his sharp business sense combined with his rich knowledge and experience in the field of clinical research AHC from strength to strength.*

## EDUCATION

- MBBS : Govt. Stanley Medical College
- MD (Pharmacology) : Govt. Madras Medical College.

## AFFILIATIONS

- **Founder :** Aurous HealthCare R&D India Pvt. Ltd.
- **Founder :** Universal Ethics Committee
- **Medical Director :** Anna University AUKBC
- **Life Member :** Indian Medical Association
- **Life Member :** Tamil Nadu Medical Council
- **Life Member :** Indian Pharmacological Society

## CLINICAL TRIAL EXPERTISE

- Vaccine Study for WHO Submission : 3500 subjects
- First in India - Anti Hangover Study
- First in India - Patented Bone Substitute
- First in India - Device for Cognitive Impairment
- Medical Investigation on AntiBacterial Sutures
- Medical Investigation on Scaffold for Burns
- 10+ Nutraceuticals launched into global market.

# DR. VT. SRIRAAM MBBS MD (PHARM)

## Founder & Managing Director



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## COMMERCIAL POSITIONING

The goal of commercial positioning is to create a unique identity for your product and establish a competitive advantage in the market. The idea is to design and execute clinical trials with study designs that align with the desired product positioning while ensuring strict compliance with national and international guidelines and mandates.

**** Scientific Validation of product claims.*** **** Internationally compliant Study Reports.***
**** Trials designed specifically for your needs.*** **** Enhanced Marketability of products***

## MEDICAL WRITING

Regulatory documents are an integral part of research, which varies with regulatory requirements and country to country. AHC provides you the best of medical writing, backed by Key Opinion Leaders and Medical Experts from the field.

**** Clinical Study Plans*** **** Informed Consent Forms*** **** Case Report Forms***
**** Investigator's Brochure*** **** Statistical Analysis Plan*** **** Interim Analysis Plan***
**** Clinical Study Report*** **** Investigation Plan (Medical Devices)*** **** Translations***

## REGULATORY AFFAIRS

AHC has been immensely successful in obtaining regulatory approvals for clinical development and commercial manufacturing of pharmaceutical, biologicals and medical device products. Our experts keep vigilant track of the constant changes in legislations to provide strategic, tactical and operational direction to expedite the development and delivery of safe and effective healthcare products.

**** Regulatory Strategy & Compliance*** **** Clinical Trial Applications*** **** Safety Reporting***
**** CDSCO - SUGAM*** **** CDSCO - MedDev Dossiers*** **** Pharmacovigilance***

## COST EFFECTIVE & CUSTOMISED CLINICAL TRIALS

AHC is a comprehensive service CRO - all our activities from documentation, medical writing, translations, investigator coordination, data management, statistical analysis, study reports - all are done in house. This allows us to provide competitive budgets suited for your needs.

We customise clinical study design to suit your products, the claims you want validated with standardised, internationally accepted assessments, questionnaires and end points.
This adds credibility and international acceptance to the clinical study results.

## INTERNATIONALLY ACCEPTED REPORTS

With a finger on the pulse of the international pharmaceutical regulations, the regulatory experts at **AHC** coordinate with the medical writing team to create **Clinical Study Reports (CSR)** that are accepted across nations. Our Clinical Study Reports are written as per the universally accepted norms of E3 guidelines, set up by the International Conference on Harmonisation (ICH).

## AN ASSOCIATION FOR LIFE

At AHC, we pride ourselves on having a continual association with our clients, surpassing trends and years. We have aided with clinical study validation and successful market launches for more than one product for each of our clients.

***An association with AHC transcends business!***

Our clients come to us years after a product launch with a scientific clarification or validation aid for advertisements and product brochures. We have even been the spokesperson for our clients for queries with bodies like ASCI –Advertising Standards Council –India. This extended relationship, our expertise and timely execution makes us Aurous HealthCare CRO the preferred R&D partner for many clients across the world.

# LET'S TALK

Aurous HealthCare was conceptualised with the intent to bridge gaps in clinical research. We are here to help you with your research questions.

We hope to open channels for honest and open conversations about your product and the research that would be designed specifically for your needs, requirements and regulatory compliance.


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