VIaTAL PHARMA CONSULTANCY

Providing Viable and Vital Solutions

Dr.Vandana Jolad Shivanagi, Founder-MD,

PhD-Leeds:UK, B-Tech-UDCT, MBA, IRQAO Approved Lead Auditor

IRQAO REGISTERED www.irqao.com INSPECTION BODY

http://www.irqao.com/Search.aspx?s=jolad

1.0 Pharma Global work Consultancy

VIaTAL Pharma Consultant is an India based Pharmaceutical all-in-one Regulatory, Pharmacovigilance, Quality, GMP, Technical Global consultant, Located in Mumbai(India). VIaTAL Pharma Consultancy is involved in a wide variety of regulatory consulting assignments with Regulated markets e.g. U.S.A, Europe, Australia etc. and Semi regulated markets e.g. India, Asia Pacific, CIS, Middle- East, Africa, Latin America, Carribeans etc.

VIaTAL Pharma Consultancy assist clients by guiding the product development in line with the country specific requirements, data generation, document compilation for submission to various Regulatory

Agencies all over the world, responding to the queries and finally obtaining the approval or registration of the product all under one roof.

Our core focus is to offer supportive services to Regulatory Departments of Pharmaceutical Companies in the field of Registering Pharmaceutical Dossier Writing. We are have been involved with all aspects of regulatory affairs, from supporting Clinical trials, bioequivalence waiver reports, validation data, Expert reports, Data for Overview, PSUR through registration activities, compilation of Pharmaceutical dossier / application for registrations of medicines and E-Filings to post-marketing regulatory obligations for Pharma Industry. We also offer 'Gap Analysis' which is a meticulous review of the dossier ready for submission.

We have excellent contacts all over India and therefore we also provide liaison services for those who wish to search for suppliers of raw materials, products and processes**,** as well as for those who wish to expand their global presence in a very telling manner. Business consultancy is provided on various aspects related **to** imports, exports, regulations, market conditions, competition, product viability, etc**.**

We also help overseas buyers for contract manufacture of various products on exclusive basis by using technical talent and expertise available with Indian manufacturers.

2.0 Why VIaTAL

Dr. Vandana, Founder and M.D. of VPC services, is herself, **having strategic experience of working directly in the UK and EU for nearly 15 years** in field of Complete Regulatory, cGMP, Quality, Clinical,Business Development, EU-QPPV.

Dr. Vandana is a Pharmaceutical Chemical Technologist graduated from worlds Top 10 prestigious University **Department of Chemical**

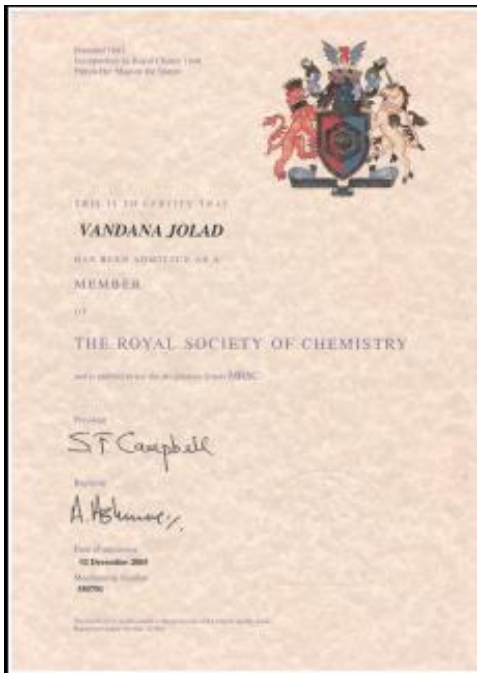
Technology, Bombay (now UICT). Who has further pursued her PhD from **University of Leeds (England)** with British Overseeas and Tetley Lupton Scholorship.

Dr. Vandana has overall 25 years of Pharma industry working directly on production shopfloor, QA/QC, Regulatory, and successful in one-to-one productive meetings with UK-MHRA,EU-EMEA, Other FDAs.

This is to certify that
Dr. Vandana Jolad Shivanagi
Santdeep Shivanagi
VJ's PAL Pharma Consultancy
604, Sakari Shivam, Nityanand Marg Rd.
Chembur Camp
Mumbai - 400074, India
is a registered patron member
of
The Council of EU Chambers of Commerce in India
For the Period
1/4/2017 to 1/3/2018
Patron Membership No: P1665

Dr. Rita Sharma — Director
Mr. Chandramouli Srinivasan — President

The Council of EU Chambers of Commerce in India
3rd Floor, Y. B Chavan Centre, Gen. J. Bhosale Marg, Mumbai 400021



VANDANA JOLAD
MEMBER
THE ROYAL SOCIETY OF CHEMISTRY

Dr. Vandana, herself, has achieved:

- 281 New product Final Registeration approvals (Regulated & ROW)
- 375 VARIATIONS FILLINGS APPROVALS
- 17 successful Bio-waiver applications
- All cGMP & Pharmacovigilance EU/MHRA/USFDA body inspections
- 62 successful ICH/cGMP audits finally product/plant – reports complied and approved by MOHs

Dr. Vandana is authorized to communicate to FDAs and Ministry of Healths, and can assist in writing for response to further information (RFI) as per client-specific requirements.

The VIaTAL working team and staff is very proactive and multitasking.

3.0 Categories in which we work

New Chemical Entities
Generics (Abbreviated New Drug Approval) OTC (Ayurvedic/ Herbal & Chemical)
Investigational New Drug (IND) Application
New Dug (NDA) Application
Investigation New Drug Approval
Biological, Blood Products
Formulations/API

3.1 Markets for which we work

Regulated markets

USA
European Union
Australia

Semi- regulated markets

Asia Pacific, Asean Countries, All CIS Countries,
Middle- East, African Countries, Latin America.

3.2 Companies with whom we work

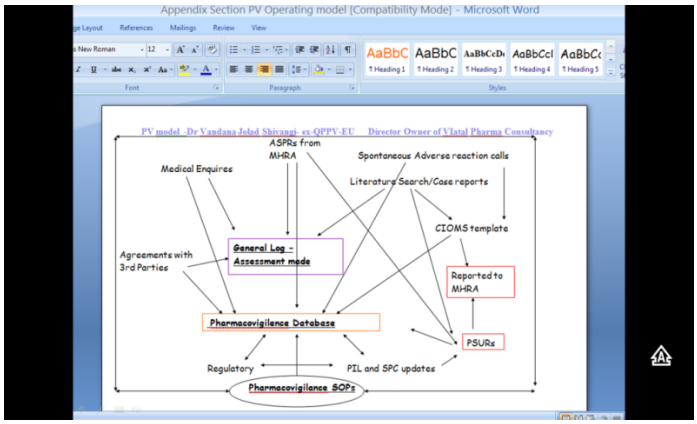
Foreign and Indian Pharma, vitamins companies and who wish to enter the Indian market and other international markets. Indian Pharma companies who wish to enter International markets. Clinical research organizations who wish to seek permission for Clinical Trials in India.

Some of the companies we associated with: to training,dossier making, received Regulatory/NON-regulated market registrations, third party ICH-GMP audits, QbD/PAT, business development – Tillomed, Blossom, Centaur, SGS, Kilitch, Akorn, TEVA, Morepen, Alembic, Hetero, Helm, Dune Medicare, Intas, Unimark, Lake-India,…etc

4.0 Services Offered

- Preparation and filing of Registration dossiers for submission to various regulatory agencies all over world (including eCTD, CTD & ACTD Format).
- Drug Master File (DMF) compilation for open and closed part.
- **Quality,Preclinical and clinical overviews** writing through literature search / published studies / articles from journals from sources.
- Assisting the clients for development of new products and data generation in line with country specific registration guidelines.
- Registration dossiers for submission to various Regulatory Agencies all over the world (including CTD format)
- **Assistance in Response to queries for submission** to the Regulatory Agencies. Regulatory Assistance in Post-Approval compliance
- Assisting the clients to **upgrade the existing products** by additional data generation to the requirements of new countries.
- Assisting in **finalization of suppliers (vendor) for active ingredients** used in various formulations.
- Assisting the clients for product claims backed with scientific literature so as to get competitive advantage.
- Assisting the clients on advertising and marketing promotional material from Regulatory perspective.
- **Renewals/ variations** (all types), change of ownership
- Performing **self ICH / cGMP Audits**, Inspection support, Final analysis reports. For clients.
- Artwork, for inner outer work assistance EXACTLY as per country-specific guidelines.
- We do also assist in opting of DCP/MRP etc. slots, market search on pivotal scale.

- **Complete Pharmacovigilance** work assistance, PSURs, signals, etc.
- **Complete API/Formulation Plant audit ISO-9001/EU-cGMP and provide indepth GAP report and strategy**



Pharmacovigilance Model Basic

- Assisting in Generation of complete company **SOPs**
- **Biowaiver expert reports**.
- We also provide **training** to cater to client-specific needs, specializing in Regulatory, GMP, GLP, GCP, Quality Management database, Pharmacovigilance.
- We aid **support Research activities** to Pharma companies.

Cases

An overview of a few of the cases handled with excellent results

1) A Goa-based topical manufacturing plant was completely audited and Report provided on EU-cGMP compliance plan for exports

Training CTD provided to Heads of Dept.

2) A large Mumbai based company asked VPC to make a superfine CTD from very old dossier typed copy about 12 years old data

VPC preliminary scrutinized the entire file starting from development to composition to Manufacturing, analysis, packing style, artwork , any clinical or toxicology studies. The company associated with CRAMS got product pilot and production batch and we compiled entire dossier with biowaiver report. 3 such dossiers were made and got fully submitted and got change of ownership transferred license.

3) A UK-based firm seeked us to audit API companies in India to be used for their formulation.

VPC studied all API company manual, set agenda as per ICH Q7A /cGMP guidleines, send checklist to company under audit, completed audit, gave analysis, report and follow on dates. The reports were accepted by UK-MHRA.

4) A Danish-based company in In India wanted us to be their specialist to travel to CPhI –EU-worlwide to get business.

We were successful in obtaining good business contacts and deals for this Danish company

5) A MNC based in India sent us request for getting all expert info to use SmPC to make final user tested leaflet assistance and primary secondary literature for some EU and PAN-ASEAN territories.

6) An oncology based Indian company had made us their prime contacts to Ministry of Healths to Tanzania, Peru, SantoDomingo, Costarica, Kenya , Panama . These are for llyophillised powdered injections and tablets. We had resolved the Response for further information in very efficient manner and obtained variation approvals, licenses for all the applications within short span of time.

7) A Chennai based company in joint collaboration with UK-firm asked us to assist with entire Pharmacovigilance set and make it compliant to inspections. We have trained, made all documents, helps them in setting PSURs, signals, CIOMS logs, Adverse reaction log. SOPs etc. Our presence was also made in the ACTUAL INSPECTIONS . It was successful

8) A antibiotic oral dosage firms company wanted us to do various Type-II complex variations for tablet diameter

We arranged to submit to EMEA with all BMR/BPR, Form Compilation, F1/F2 expert invitro-dissolution report, tablet diameter trend analysis sheet and 3 production batches analysis and justification for the change. Successsful in getting type -II approval

9) A International MNC Company in India were seeking to train their senior managers on New Regulatory approach for Regulated and ROW Markets

VPC successfully trained for a week complete Regulatory overview and Modules 1-5 step by step for a batch of 50 candidates

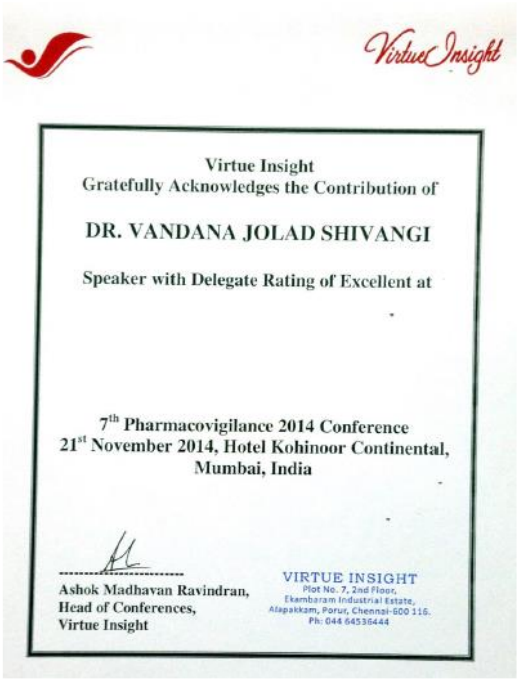
---

For further information, please contact Mumbai Office

VIaTAL PHARMA CONSULTANCY
Providing Viable and Vital Solutions

<vjolad@yahoo.com>
Visit us at – www.viatalpharma.com

GALLERY of our Credentials and Works



Virtue Insight

Virtue Insight
Gratefully Acknowledges the Contribution of

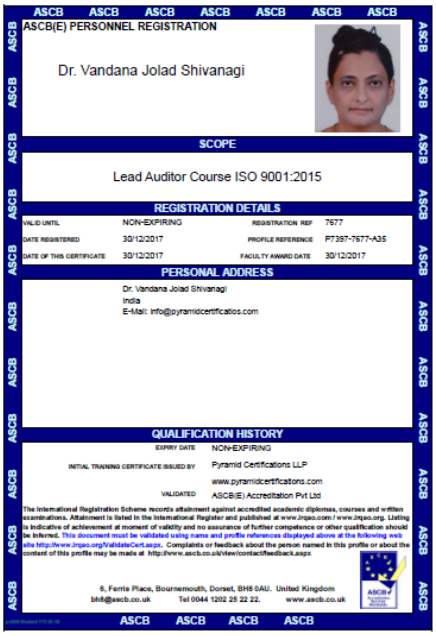
DR. VANDANA JOLAD SHIVANGI

Speaker with Delegate Rating of Excellent at

7th Pharmacovigilance 2014 Conference
21st November 2014, Hotel Kohinoor Continental,
Mumbai, India

Ashok Madhavan Ravindran,
Head of Conferences,
Virtue Insight

VIRTUE INSIGHT
Plot No. 7, 2nd Floor,
Ekambaram Industrial Estate,
Alapakkam, Porur, Chennai-600 116.
Ph: 044 64536444



ASCB(E) PERSONNEL REGISTRATION

Dr. Vandana Jolad Shivanagi

SCOPE

Lead Auditor Course ISO 9001:2015

REGISTRATION DETAILS

VALID UNTIL	NON-EXPIRING	REGISTRATION REF	7677
DATE REGISTERED	30/12/2017	PROFILE REFERENCE	P7397-7677-A35
DATE OF THIS CERTIFICATE	30/12/2017	FACULTY AWARD DATE	30/12/2017

PERSONAL ADDRESS

Dr. Vandana Jolad Shivanagi
India
E-Mail: info@pyramidcertifications.com

QUALIFICATION HISTORY

EXPIRY DATE	NON-EXPIRING
INITIAL TRAINING CERTIFICATE ISSUED BY	Pyramid Certifications LLP
	www.pyramidcertifications.com
VALIDATED	ASCB(E) Accreditation Pvt Ltd

The International Registration Scheme records attainment against accredited academic diplomas, courses and written examinations. Attainment is listed in the International Register and published at www.inpao.com / www.inpao.org. Listing is indicative of achievement at moment of validity and no assurance of further competence or other qualification should be inferred. This document must be validated using name and profile references displayed above at the following web site http://www.inpao.org/ValidateCert.aspx. Complaints or feedback about the person named in this profile or about the content of this profile may be made at http://www.ascb.co.uk/view/contactfeedback.aspx

6, Ferris Place, Bournemouth, Dorset, BH8 0AU. United Kingdom
bhb@ascb.co.uk Tel 0044 1202 25 22 22. www.ascb.co.uk

INSTITUTE FOR TECHNOLOGY AND MANAGEMENT

CERTIFICATE OF COMPLETION

SOUTHERN NEW HAMPSHIRE UNIVERSITY

CERTIFIES THAT

Dr. Vandana Jolad Shivangi

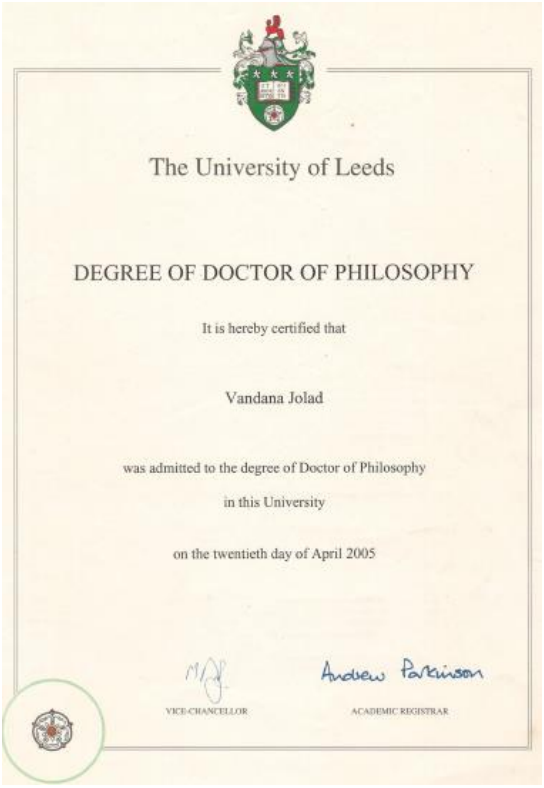
HAS COMPLETED THE

Master of Business Administration

PROGRAM

GIVEN AT MUMBAI, INDIA IN JUNE 2014

Southern New Hampshire University



The University of Leeds

DEGREE OF DOCTOR OF PHILOSOPHY

It is hereby certified that

Vandana Jolad

was admitted to the degree of Doctor of Philosophy

in this University

on the twentieth day of April 2005

Andrew Parkinson

VICE-CHANCELLOR ACADEMIC REGISTRAR

MTM

This is to certify

Dr. Vandana Jolad Shivangi

PhD-UK, B. Tech-UDCT, MRSC-UK, MBA, ISO- 9001 LEAD AUDITOR

of

VITAL PHARMA CONSULTANCY

Providing Viable and Vital Solutions

Conducted a session on 11th Jan 2018

On

Medicinal Products - Quality, Safety & Efficacy

for

MTM SHIP MANAGEMENT INDIA PVT. LTD.

4th Floor, Gala Impecca, Next to Courtyard by Marriott, J.B. Nagar, Andheri East, Mumbai - 400059

Capt. Jaideep Dhamankar
Country Head

What should dossier report approval look like....

MHRA

MODULE 4 & 5 CLINICAL/ NON CLINICAL ASSESSMENT

A satisfactory clinical and non-clinical overview (expert report) has been written by an appropriately, Dr Vandana Jolad, whose CV has been provided.

Dr Ewa Celinska
Medical Assessor
Updated by: Dr Elisabeth Girardin
Medical Assessor
November 2010

What should biowaiver report approval look like....

MHRA

MODULE : BIO-EQUIVALENCE WAIVER ASSESSMENT

A satisfactory Biowaiver invitro dissolution (expert report) has been written by an appropriately, Dr Vandana Jolad, whose CV has been provided.

Clinicall Assessor
Updated by: MHRA
Medical Assessor
March 2011

CERTIFICATE OF ATTENDANCE

THIS CERTIFICATE IS PRESENTED TO

50 FRESH PHARMA GRADUATES – TEVA PHARMA

FOR ATTENDING 1 day SEMINAR/WORKSHOP ON → first hand Overview of Global Regulatory Affairs and CTD modules by Dr. Vandana

Rajashri Ojha
Founder and Founder Director, Raaj GPRAC

Dr. Vandana Jolad Shivangi
Pharma Consultant, Ph D
Expert trainer

DATE: 10th Jan 2014
PLACE: Mumbai

Meeting with Confederation Danish Industry

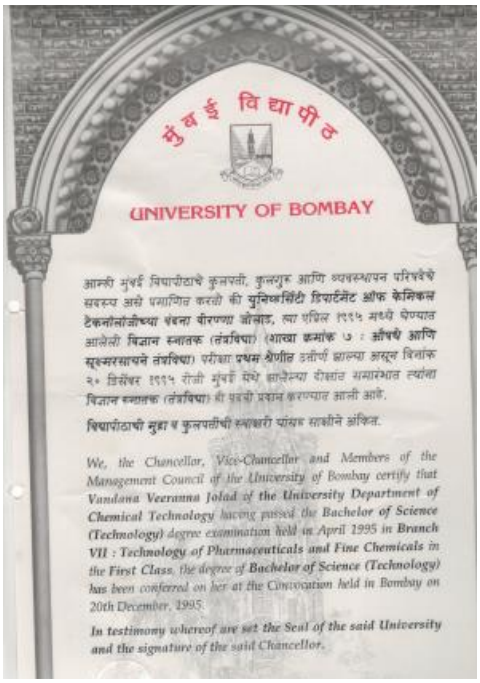
√ Confederation of Danish Industry has organized th followed by B2B meetings.

Meeting at the Business Region Goteborg

May 26, 2017.

Meeting at the Indian Embassy in Stockholm, Sweden

The E m orga meet of v deleg the premi Sanjo CEO Unlim pres highlig



मुंबई विद्यापीठ

UNIVERSITY OF BOMBAY

आम्ही मुंबई विद्यापीठाचे कुलपती, कुलगुरु आणि व्यवस्थापन परिषदेचे सदस्य असे प्रमाणित करतो की **युनिव्हर्सिटी डिपार्टमेंट ऑफ केमिकल टेकनोलॉजीच्या** चंदना वीरण्णा जोलाड, या एप्रिल १९९५ मध्ये घेण्यात आलेली **विज्ञान स्नातक (तंत्रविद्या)** (**शाखा क्रमांक ७ : ऑप्टी आणि सूक्ष्मरसायने तंत्रविद्या**) परीक्षा **प्रथम श्रेणीत** उत्तीर्ण झाल्या असून दिनांक २० डिसेंबर १९९५ रोजी मुंबई येथे झालेल्या दीक्षांत समारंभात त्यांना विज्ञान स्नातक (तंत्रविद्या) ही पदवी प्रदान करण्यात आली आहे.

विद्यापीठाची मुद्रा व कुलपतींची स्वाक्षरी यांसह साक्षीने अंकित.

We, the Chancellor, Vice-Chancellor and Members of the Management Council of the University of Bombay certify that ***Vandana Veeranna Jolad*** *of the* ***University Department of Chemical Technology*** *having passed the* ***Bachelor of Science (Technology)*** *degree examination held in April 1995 in* ***Branch VII : Technology of Pharmaceuticals and Fine Chemicals*** *in the* ***First Class****, the degree of* ***Bachelor of Science (Technology)*** *has been conferred on her at the Convocation held in Bombay on 20th December, 1995.*

In testimony whereof are set the Seal of the said University and the signature of the said Chancellor.

Safeguarding public health

MHRA

Certificate of Attendance

Vandana Jolad

has attended

Practical Workshop on eCTD Implementation Seminar

5th February 2008

4.75 CPD Points

Providing Expert Advice for Healthcare Professionals