Samarth Rural Educational Institute's
SAMARTH COLLEGE OF PHARMACY
ApprovedbyP.C.I.NewDelhi,D.T.E.Govt.ofMaharashtra&Affiliatedto
D.B.A.T.U. Lonere,M.S.B.T.E. Mumbai.
OnKalyanNagarHighwayA/P-Belhe,Tal:Junnar, Dist:Pune-412410,Maharashtra,India

Dr. Jitendra Kumar Badjatya

Associate Professor

E-Mail: jeetbadjatya@gmail.com

Qualification: Ph.D. (Pharmaceutical Sciences) M.Pharm. (RA)

PROFESSIONAL EXPERIENCE:

- **Total Experience of Regulatory Affairs** in pharmaceutical organization: **(15 Years)**
- **Editor-in-chief –IJDRA Journal, Speaker, Guest Lecturer**
  Dec, 2019 – Current
- **Manager – Regulatory Affairs -** Umedica Laboratories Pvt, Ltd., Vapi, Gujarat.
  Feb, 2017 – Dec, 2019
- **Deputy Manager – Regulatory Affairs -** Montajat Pharmaceuticals Co. Ltd., Dammam, Saudi Arabia October 2013 – Current
- **D. Regulatory Affairs Specialist-** Health Biotech Ltd., Chandigarh, India
  July 2011 – August 2013
- **E. Manager - Regulatory Affairs-** Brawn Laboratories Ltd. (Fine Pharmachem), New Delhi, India June 2010 – July 2011
- **F. Officer - Regulatory Affairs-**MGRM Medicare Ltd., New Delhi, India
  Jan 2009 – May 2010
- Currently working as an Associate Professor 2 feb 2023 in Samarth College of Pharmacy, Belhe, Pune.

SEMINARS/WORKSHOPS/PRESENTATIONS/PUBLICATIONS:

- Ph.D. (Pharmaceutical Sciences): "Preparation of Non-infringement opinion and Submission of Dossier in C.T.D. format for taking Marketing approval of Tianeptine sodium Cap. (12.5 mg) in US, U.K, and Russia."
- M. Pharm (RA): "Preparation and Submission of Dossier in C.T.D. format for taking Marketing approval of Metronidazole Tablet (500 mg) in US, EU and Brazil on behalf of Symbiotic Pharma (India) Ltd."

TRAINING, WORKSHOP AND DIPLOMA

- ***1***. Advanced Post Graduate Diploma in Clinical Research
- Institute: Cliniminds , Noida, India; Duration: Six months (Sept., 2014 - Feb, 2015).
- 2. PG Diploma in Drug Regulatory Affairs

- Institute: IPM, Mumbai, India; Duration: Six months (Aug., 2014 - Jan, 2014).
- 3. Diploma course in “Scientific and Technical writing”
- Institute: NSTC, Noida, India; Duration: Six months (Jan., 2013 - June, 2013).
- 4. Diploma course in “CTD and eCTD in Formulation”
- Institute: Raaj GPRAC, Thane, Mumbai, India; Duration: Four months (Oct., 2012 - Jan, 2013).
- 5. Workshop on "Organization of CTD and Technical CMC- Writing/Review skills"
- Institute: Raaj GPRAC, Thane, Mumbai, India; Duration: Two days (26-27 Oct., 2012).
- 6. Training on eCTD Submissions (US and EU)
- Institute: Raaj GPRAC, Thane (W), Mumbai, India; Duration: Two days (15-16 Nov., 2014).
- 7. Training on "Patenting System in India"
- Institute: NIIPM, Nagpur, India; Duration: Two days (06-07 Oct., 2008).
- 8. Training on “Liquid, Tablet Section and Testing Laboratory”
- Company: Clinton Pharmaceuticals, Jaipur (Raj.) India; Duration: Two months (20 July-20 Sept 2006)
- 9. Certificate on “Regulatory Affairs Certification (RAC Global)”
- Organization: RAPS, Rockville, Maryland, United States; Validity 1 Year

ACHIEVEMENTS

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- GATE Score: 325; RAC Global, UGC–JRF Research Scholar; Registered Pharmacist.
- Simplified filing and first successfully initiated formats CTD, ACTD, NeeS, and eCTD.
- PAPER PUBLICATIONS
- Badjatya JK, Jangid A, Dodiya P, Soni S, Parekh A, Patel D, Patel J. (2022) Comparative study of Regulatory requirements of Drug Product in Emerging market. Int J Drug Reg Affairs, 10(1):52-81.DOI: 10.22270/ijdra.v10i1.510
- Pooja Chaudhari and Badjatya, J. K. (2021) “Current Regulatory requirements for registration of nutraceuticals in ASEAN”, International Journal of Drug Regulatory Affairs, 9(4), pp. 37-45. doi: 10.22270/ijdra.v9i4.501.
- Badjatya, J. K., Pooja Chaudhari and Bheda, A. (2020) “Prevention, treatment and cure for COVID-19”, International Journal of Drug Regulatory Affairs, 8(3), pp. 36-55. doi: 10.22270/ijdra.v8i3.406.
- Pooja Chaudhari and Badjatya, J. K. (2019) “Good Practices in Management of deficiencies in CTD dossier and comparative study for US, EU and Australia”, International Journal of Drug Regulatory Affairs, 7(4), pp. 40-55. doi: 10.22270/ijdra.v7i4.371.
- Patel, P., Badjatya, J. K. and Hinge, M. (2019) “Comparative study of Regulatory requirements of Drug Product in Emerging market”, International Journal of Drug Regulatory Affairs, 7(3), pp. 48-62. doi: 10.22270/ijdra.v7i3.350.
- Shah, S. and Badjatya J.K. (Dec. 2018) “Preliminary Requirement for Filing Application in US”. International Journal of Drug Regulatory Affairs, Vol. 6, no. 4 pp. 1-8.
- doi: https://doi.org/10.22270/ijdra.v6i4.276

- Patel, D., Badjatya J.K, and A. Patel. (June 2017) “Preparation and Review of Chemistry, Manufacturing and Control (CMC) Sections of CTD Dossier for Marketing Authorization”. International Journal of Drug Regulatory Affairs, Vol. 5, no. 2, pp. 1-12,
- doi: https://doi.org/10.22270/ijdra.v5i2.196
- Joseph Lincy, George Mathew, Malaviya Kalpesh K, Chacko Bincy K, Badjatya Jitendra K (June 2016). Comparative study for Generic drug approval process and their registration as per CTD in Europe, USA and Brazil. International Journal of Drug Regulatory Affairs, 4(2), 1-9.
- Badjatya J.K, Saraswat Rohit (April 2016). Requirement of Dug product registration in Russia. International Journal of Innovative Science and Technology, 1(1), 8-15.
- Agarwal Pooja, Badjatya J.K (Dec. 2015). DMF filing in US, Europe and Canada. International Journal of Drug Regulatory Affairs, 3(4), 9-17.
- Bhave C, Dolhare N, Badjatya J K. (March 2015). Marketing authorization application (MAA) for Europe market. International Journal of Drug Regulatory Affairs, 3(1), 88-91.
- Anusha, Dureja H*, Pandey P, Badjatya J.K. (Sept. 2014). Self-Medication In Relation To Health Locus of Control. International Journal of Drug Regulatory Affairs, 2(3), 62-66.
- Tripathy S, Murthy P.N, Patra B.P, Dureja H, Badjatya J. K. (June, 2014). A Pragmatic way to sustain in Generic Pharma environment: PLCM through Regulatory strategies. International Journal of Drug Regulatory Affairs, 2(2), 31-48.
- Mohidekar S, Maharao V, Badjatya J. K. (June 2014). Common deficiency raised by various regulatory agencies. International Journal of Drug Regulatory Affairs, 2(2), 5-6.
- Prajapati V, Goswami R, Makvana P, Badjatya J. K. (March 2014). A Review on Drug approval process for US, Europe and India. International Journal of Drug Regulatory Affairs, 2(1), 1-11.
- Tannan S.K., Badjatya J. K. (Oct 2013). TRIPS and Indian Pharmaceutical Industry. International Journal of Drug Regulatory Affairs, 1(3), 8-14.
- Kashyap P, Duggal E., Budhwar P., Badjatya J. K. (Oct 2013). Marketing authorization of Generic Drug: Global issue and challenges. International Journal of Drug Regulatory Affairs, 1(3), 1-7.
- Meena M., Badjatya, J.K (August 2013). Patent v/s Monopoly-A case study. International Journal of Drug Regulatory Affairs, 1(2), 59-60.
- Ashara K.C., Paun J.S., Soniwala M.M., Chavada J.R., Badjatya J. K. (August 2013). Nanoparticulate Drug delivery system: A novel approach. International Journal of Drug Regulatory Affairs, 1(2), 39-48.
- Kashyap P, Duggal E., Budhwar V., Nanda A., Badjatya J. K. (August, 2013). Drug Approval Process: A Contrastive Approach. International Journal of Drug Regulatory Affairs, 1(2), 11-19.
- Badjatya, J.K & Bodla, R.B. (August 2013). Harmonization & advancement in Pharmaceutical Industry. International Journal of Drug Regulatory Affairs, 1(2), 7-10.
- Badjatya, J.K & Bodla, R.B. (August 2013). Drug Product Registration in Semi-Regulated Market. International Journal of Drug Regulatory Affairs, 1(2), 1-6.

- Badjatya, J.K (June 2013). Overview of Drug Regulatory Affairs and Regulatory Profession. International Journal of Drug Regulatory Affairs, 1(1), 1-4.
- Badjatya, J.K (2013, March). Generic Drugs Market: Brand versus Generic. Journal of Drug Delivery & Therapeutics, 3(2), 222-226.
- Badjatya, J.K (2013, March). Overview of Drug Registration requirements for Pharmaceuticals in Emerging Market. Journal of Drug Delivery & Therapeutics, 3(2), 227-232.
- Badjatya, J.K, Bodla, R. & Musyuni, P. (2013, January). Export Registration of Pharmaceuticals in Rest of World Countries (ROW). Journal of Drug Delivery & Therapeutics, 3(1), 61-64.
- Badjatya, J.K, Bodla, R.B. & Soni, P. (2012). A Method for Spectrophotometric determination of Tianeptine in Bulk and Capsule Dosage Form. Asian Journal of Pharmacy and Medical Science, 2 (5), 83-85.
- Badjatya, J.K, Bodla, R.B. & Moon, U.B. (2011). Enhancement of solubility of Fenofibrate by using different Solubilization techniques. Asian Journal of Pharmacy & Life Science, 1 (2), 144-148.
- Badjatya, J.K, Bodla, R.B., Solanki, S. & Kumar, D. (2011). Enhancement of solubility of Paclitaxel by Solid dispersions techniques. Asian Journal of Pharmacy & Life Science, 1 (2), 156-160.
- Badjatya, J.K, Bodla, R.B. & & Kumar, S. (2012). Preparation of dossier for the new formulation as per ICH EU-CTD format: A Review. Asian Journal of Pharmacy and Medical Science, 2 (5), 86-88.
- Badjatya, J.K & Bodla, R.B. (2012). Enhancement of dissolution of poorly water soluble Aceclofenac by preparing Nanoparticles. Inventi rapid:NDDS, 2012(1),1-2.

MAGAZINE ARTICLES

- Badjatya JK. Regulatory requirements and registration process of Generic drugs in China. Pharmatutor. [Internet]. 2015 Sept [cited 2015 Sept 12]; [about 9pp.]. Available from: http://www.pharmatutor.org/articles/regulatory-requirements-registration-process-generic-drugs-china
- Badjatya JK. Regulatory essentials-Generic drugs in China. Ingredients South Asia. 2015 Sept; 56-58.
- Badjatya JK. Regulatory requirements for Generic drugs. Ingredients South Asia. 2015 April; 57-64.
- Prajapati V, Goswami R, Makvana P, and Badjatya JK. Drug approval process–US, Europe and India. Ingredients South Asia. 2014 Dec; 7(22):69-74.
- Badjatya JK. Drug product registration in Semi-regulated nations. Ingredients South Asia. 2014 Aug; 7(22):46-50.
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- SEMINAR/CONFERENCE/WEBINAR ATTENDED:

- “Webinar on “Use of QR code in doctor & patient engagement by pharma” (24th April, 2022) CPhE.
- Webinar on “GCC Regulatory Affairs Pharma Summit” by PRA consultancy, Hubplus events at Dubai-UAE.
- Webinar on “Awareness course on recent changes in Indian and Global Regulatory Landscape” at NIPER , Hyderabad on 29th march, 2022
- Webinar on “Free GMP QMS Webinar from GMP publications by GMP Bootcamp on 2nd march, 2022.
- Webinar on “15th Drug Discovery Innovation Programme” by WorldBI on 2nd march, 2022.
- Webinar on “17th Clinical Trials Innovation Programme” By world BI on 3rd march, 2022.
- Webinar on “5th Annual Pharma Regulatory Summit 2022 “by Virtue insight on 9th & 10th March, 2022.
- Webinar on “Pharma Investigation & CAPA” by Blutech Media on 24th-25th February 2022.
- Training on Quality by Design (QBD)” By Blutech Media 16th- 17th December 2021.
- Webinar on “Introduction to FDA human drug review and approval basics” by US FDA on 30 November 2020.
- Webinar on Pharmaceutical Regulatory Summit in Africa” by Pharma Reg Afri Summit at Dubai-UAE on 14 & 15th September 2021.
- Webinar on “GCC Regulatory Affairs Pharma Summit” by GCC, PRA consultancy, Hubplus at Dubai-UAE on 22nd & 23rd march, 2021.
- 8th Annual Global Pharma Regulatory Summit (29th – 31st May 2019) at THE LALIT, Mumbai
- 7th Annual Global Pharma Regulatory Summit (30 May-01 June, 2018) at Westin, Mumbai
- Novel Formulation Strategies (12-13 April 2018) from Select Biosciences India (SELECTBIO) at Mumbai.
- National seminar on “Reformation of Pharma Education in India” (11 Nov, 2012) at Lodi Road, New Delhi.
- India Pharma convention by UDF on “Challenges & Issues in Pharmaceutical sector in India” (12 Feb, 2012) at DIPSAR, New Delhi.
- “Webinar on Validation” (30 April, 2011) by SMPIC at NIPER, SAS Nagar, Mohali, Punjab.
- Workshop (2 days) on “Organization of CTD and Technical CMC –Writing & Review Skills” by Raaj GPRAC at Hotel Satkar Residency, Thane.
- Training Programme on “Patenting System in India” (6-7 Oct, 2008) at National Institute for Intellectual Property Management, Nagpur.
- “Seminar on Validation” (30 April, 11) by SMPIC at NIPER, SAS Nagar, Mohali , Punjab.
- “Seminar on Risk analysis” (26 August, 2011) by SMPIC at NIPER, SAS Nagar, Mohali, Punjab.
- National Symposium on “Current Challenges in Pharmaceutical Education & Research” (29 Sept, 2011) at Globus College of Pharmacy, Bhopal (MP).

- Seminar on “Current Good Manufacturing Practices” (2 & 3 April, 2012) by SMPIC at NIPER, SAS Nagar, Mohali, Punjab.
- Seminar on “Export Registration of Pharmaceutical Products” (16 June, 2012) by SMPIC at NIPER, SAS Nagar, Mohali, Punjab.
- International Conference on “Strategies on Sustainable development in India” (17 & 18 Nov, 2012) at Shri Jagdishprasad Jhabarmal Tibrewala University, Jhunjhunu (Raj.)
- 2nd Annual Conference of Society of Pharmaceutical Education & Research (9 March, 2013) on “NexGen Health Care Scenario: Innovative Research Endeavor in Pharmaceutical Sciences for Better Patient Compliance” at Convention Centre, Jamia Hamdard, Hamdard Nagar, New Delhi.
- National Seminar on “Industry demand from Pharmacy Youth” (22 & 23 Feb, 2013) at Innovative College of Pharmacy, Greater Noida (UP).
- National Symposium on “ADR monitoring & Pharmacovigilance” (9 & 10 Feb, 2013) at ALT Centre, Ghaziabad (UP)

POSTER PRESENTATION:

- Poster presentation in National Symposium on “A review on ICH-CTD format requirements for the preparation of Dossier of Generic Formulation” (29 sept, 2011) at Globus College of Pharmacy, Bhopal.
- Poster presentation in 2nd Annual Conference of Society of Pharmaceutical Education & Research (9 March, 2013) on “Generic Drugs Market – Brand versus Generic” at Convention Centre, Jamia Hamdard, Hamdard Nagar, New Delhi.
- Poster presentation in India Pharma Convention by UDF on “Overview of Pharmaceutical Drug Regulatory Affairs & Regulatory profession” (12 Feb, 2012) at DIPSAR, New Delhi.
- Poster presentation in National seminar on “Roles of Regulatory Affairs in Pharma Education in India” (11 Nov, 2012) at Lodi Road, New Delhi.

ORAL PRESENTATION:

- Role of Regulatory Affairs in Pharmaceutical Industry on 10th of July 2021 for KIETS School of Pharmacy, KIETS group of Institutions, Ghaziabad, Delhi NCR.
- Technical dossier Filing requirements for Emerging market on 3rd July,2021 for K.B Institute of Pharmaceutical Education and Research, Gandhinagar.
- Lecture delivered in Workshop on “Requirement of CTD (CMC) section of Technical Dossier for Regulated market.” (22 Oct, 2019) at School of Pharma. Sciences, DPSRU, New Delhi, India.
- Lecture delivered on “General requirement for Registration of Pharmaceuticals for Emerging Countries” (23 Oct, 2019) at Amity Institute of Pharmacy (AIP) - Amity University, Noida, India.
- Speaker in Quality Improvement Program on “Technical requirement for filing an application in ROW Countries” (25th-29th March 2019), at DIPSAR, New Delhi, India.

- Speaker in 2nd Annual Pharma Regulatory Summit 2019 (14th March 2019), Kohinoor Continental Hotel, Mumbai, India.
- Lecture delivered on “Pharmacy Profession in India and advanced countries” (16-17 Dec, 2017) in Refresher course for Registered Pharmacist” at ROFEL Shri G M Bilakhia College of Pharmacy, Vapi, Gujarat, India.
- Speaker in Para Injecto 2nd Annual conference, (09-10 Nov,2017) at Hotel-Goldfinch, Mumbai, India
- Lecture delivered on “Pharma Regulatory Affairs: Roles & Responsibilities” & “Common Technical Document: Presentation & Format of a Dossier” (13 Dec, 2013) at Deptt. Of Pharmaceutics, Jamia Hamdard, New Delhi, India.
- Paper Presented in International Conference on “Harmonization & advancement in Pharmaceutical Industry” (17 Nov,2012) at Shri Jagdishprasad Jhabarmal Tibrewala University, Jhunjhunu (Raj.), India.
- Paper Presented in National Symposium on “Overview of Registration Requirements for Pharmaceuticals” (9 & 10 Feb, 2013) at ALT Centre, Ghaziabad (UP), India.
- Oral Presentation (II Prize) in National Seminar on “Requirements of Drug Regulatory Affairs in Pharmaceutical Profession” (22 & 23 Feb, 2013) at Innovative College of Pharmacy, Greater Noida (UP), India.
- Lecture delivered on “Common Technical Document” & “eCTD” (21 Dec, 2012) at in Cliniminds, Noida (UP), India.
- Lecture delivered on “Pharma Regulatory Affairs: Roles & Responsibilities” at Clinovision, New Delhi, India.
- Lecture delivered on “Pharma Regulatory Affairs: Roles & Responsibilities” & “Technical Requirements for Filing an application in ROW Countries” at DIPSAR, Delhi University, New Delhi, India.
- Lecture delivered on “Pharma Regulatory Affairs: Roles & Responsibilities” & “Technical Requirements for Filing an application in ROW Countries” at Harlal Institute of Management & Technology, Greater Noida, India.
- Lecture delivered on “Pharma Regulatory Affairs: Roles & Responsibilities” & “Technical Requirements for Filing an application in ROW Countries” at Llyod college of Pharmacy, Greater Noida, India.
- Lecture delivered on “Pharma Regulatory Affairs: Roles & Responsibilities” & “Common Technical Document: Presentation & Format of Dossier” at Lovely Professional University, Phagwara, Punjab, India.
- Lecture delivered on “Pharma Regulatory Affairs: Roles & Responsibilities” & “Common Technical Document: Presentation & Format of Dossier” at Maharshi Dayanand University, Rohtak, India.

DISTINCTIVE HIGHLIGHTS:

- Registered as External examiner/Mentor in some reputed colleges/universities as:
- ROFEL Shri G. M. Bilakhia College of Pharmacy
- Ramanbhai Patel College of Pharmacy (RPCP), Anand, Gujarat
- School of Pharma. Sciences, DPSRU, New Delhi
- Lovely professional University, Punjab
- JSS college of Pharmacy, Ooty.
- JJT University, Jhunjhunu, Raj

PROFESSIONAL AFFILIATIONS:

- Computer software: PharmaReady, eSubmissionExpress, eCTD Office, Nitro Pro 10, Adobe Acrobat, MS Office 2003-2010, Internet (Patent search - esp@cenet, WIPO,USPTO and Web surfing).
- Language Proficiency: English (Full professional), Hindi (Native), Arabic (Elementary)