T.G. Venkateshwaran, Ph.D. $

Email : venkattg@merck.com $

Executive Summary

Highly motivated, skilled and seasoned leader with in-depth experience in CMC development, quality and manufacturing. Proven leader with experience in managing and leading 100+ global team members and a portfolio of 60+ compounds on a global basis. Provided development (analytical and formulation), regulatory and quality leadership in directing all required product focused activities and resources, creating optimal development, regulatory and quality strategies for both commercial and developmental products. Adept individual with excellent oral and written communication skills. Balances available resources to prioritize activities and achieve the strategic goals of the organization. Skillfully set strategic vision and collaborate with key individuals to cultivate alliances and form highly effective/efficient teams to develop execution tactics and achieve results. Recognized as an effective leader, strategic thinker, and trailblazer who constantly drives the teams to think of innovative/out-of-the box approaches to resolve challenges. Recognized subject matter expert in Quality by Design.

Education

Certified Six Sigma Black Belt (CSSBB), Villanova University, November 2009
Ph.D., in Pharmaceutical Sciences: College of Pharmacy, University of Georgia, Athens, Georgia.
B. Pharm. (Honors) - Birla Institute of Technology and Science, Pilani, India.

Professional Experience

FDA Pharmaceutical Science and Clinical Pharmacology Advisory Committee – Non voting industry member (11/2019- 10/2023)

Merck Research Laboratories Ltd, Westpoint, Pennsylvania, USA
Associate Vice President and Global Head, Global Regulatory Affairs – CMC Biologics, Policy, and Devices/Drug-Device Combination Products (10/2016 - present)

Executive Director and Global Head, Global Regulatory Affairs – CMC Biologics (11/2015 – 9/2016)

- Provide regulatory CMC leadership (biologics, medical devices and combination products) and manage a team of approx. 10 people across 4 sites, with a portfolio of approximately 10-12 approved biologics and 30 combination products.
- Lead and manage China CMC and Japan CMC regulatory teams through a matrix relationship. Manage CMC aspects of entire Merck China portfolio. Responsible for influencing activities in China and end to end life cycle management.

- Build, manage and lead all regulatory CMC aspects of lifecycle management including regulatory conformance. Mentor and coach team members to develop future pool of leaders with regulatory capability/expertise.
- Build, manage and develop Global CMC regulatory policy team to influence CMC policy and implement novel technologies of the future
- Regulatory franchise lead for Keytruda, Merck's immuno-oncology blockbuster. Helped stabilize the lifecycle management aspects of Keytruda including managing the Supply chain growth to support 100-150% growth year over year.
- File and obtain approval of 4 BLA's and 2 NDA's in 1.5 years
- Regulatory compliance/conformance activities for entire portfolio
- Accomplishments include approval and stabilization of Keytruda portfolio of changes, including critical issue resolution to maintain supply of the drug in the market, resolve quality and regulatory conformance challenges on Women's health products to maintain product supply. Establish and build the Medical devices and combination products team to support the portfolio of products.
- Actively involved in development of facility of future concept for the ! manufacturing of biopharmaceuticals, including development of modular manufacturing, end to end single use facility concept and continuous ! manufacturing for biopharmaceutical and pharmaceutical products. !

Hoffman L. Roche Pharmaceuticals, Basel, Switzerland,
Senior Group Director and Global Head, Marketed Products, **Pharma Technical** $
Regulatory Affairs (06/2014 – 10/2015) $

• Provide leadership and manage a global group of 100+ people with a portfolio of approximately 60+ compounds in various phases of the post approval lifecycle, globally. Leadership of all aspects of global CMC regulatory and lifecycle maintenance strategies for new API and drug products including antibody drug conjugate toxins and linkers. This includes interacting with global Health Authorities and managing regulatory scientists who develop CMC strategies and prepare CMC information for lifecycle management.
• QbD implementation within Roche and its utilization in all aspects of product development (including regulatory filings). Chair of the QbD committee and oversaw the development of principles for QbD implementation including development of appropriate control strategy using in process measurements, development of feedforward and feedback loops, development of analytical techniques for in process measurements including particle size measurements, infrared techniques etc,
• Actively advocated and championed the use of continuous manufacturing and early adoption of the technology for products. In conjunction with team developed the control strategy, quality approaches and regulatory pathway for filing of the technology for a product in late phase of development.
• Accomplishments include establishing of the outsourcing strategy for tail-end compounds, streamlining the content and submission of eCTD baselines for legacy/tail-end products, divestments of tail end products, Sponsor and also lead a number of initiatives to increase efficiency and effectiveness of the organization

GENENTECH (A Member of the Roche Group), South San Francisco, CA $
Senior Group Director, Pharma Technical Regulatory Affairs, (09/2013 - 06/2014) $
Group Director, Pharma Technical Regulatory Affairs (09/2010 to 08/2013) $
Global head of Regulatory Policy– Pharmaceuticals for Roche, and the Leader of $
the development CMC regulatory group –at Genentech (South San Francisco site). $

- ! Identify key topics that are important for small molecule development (QbD, continuous manufacturing, clinically relevant test methods etc.) and develop strategies to influence external environment (both in a leadership role and as a participant)
- ! Manage all aspects of global CMC regulatory and development strategies for new API and drug products including antibody drug conjugate toxins and linkers. This includes interacting with global Health Authorities and managing regulatory scientists who develop CMC strategies and prepare CMC information for clinical and marketing applications.
- ! QbD implementation within Roche and its utilization in all aspects of product development (including regulatory filings). Chair of the QbD team and championed the implementation of continuous manufacturing pre-as well as post approval for selected products.
- ! Accomplishments include establishing the development group at SSF site, establishing the QbD framework at Genentech for pharmaceuticals, approval of first NDA (Erivedge®) at Genentech, Filed and obtained approval of BLA/MAA for an antibody drug conjugate to the FDA/EMA and in global markets, Develop the plan for influencing in emerging markets (particularly China) for pharmaceuticals, Sponsor and also lead a number of initiatives to increase efficiency and effectiveness of the organization (technical regulatory strategy document. Core dossier, model documents, combination products and right CMC strategy etc.)

PFIZER PHARMACEUTICALS (FORMERLY WYETH), Collegeville, PA
Senior Director, Pharma New Product Quality Operations (12/07 – 09/2010)

Responsibilities encompass all quality aspects relating to the development of pharmaceuticals from the late learn through confirm and TD&T process. Collaborate with the team members to define and execute a product quality strategy assure the incorporation of quality into the design of products. Specific responsibilities include:

- ! Lead the team Real Time Release implementation initiative and collaborate with the manufacturing site to develop quality systems in line with ICH Q10.
  - ! This included the development of a process that was semi-continuous and introduction of a control strategy using in-process measurements -Near Infrared spectroscopy, particle size measurements and process monitoring along with eMBR implementation facilitating the release of product within hours after manufacture.
- ! Quality Risk Management (QRM) – Developed the framework and championed the use of QRM during mid/late stage pharmaceutical development

- ! Ensuring that quality by design concepts are incorporated in development .
- ! In collaboration with development personnel and the Global Technical team (GTT), develop a strategy with to utilize QbD concepts during new product development
- ! Support the development and maintenance of the QbD guide and develop strategies to standardize the implementation of concept across Wyeth
- ! Influence external environment by participating in external trade organizations (both in a leadership role and as a participant) – Chair, AAPS CMC Focus Group, Member ISPE Technical Documentation subcommittee, Speaker at various forums
- ! Standardized approaches by collaborating with cross functional teams to develop CMC templates for regulatory documents
- ! Ensure development activities are in compliance with existing quality systems and processes. Identify gaps (if any) observed and proactively address deficiencies in systems/processes.
- ! Recommend, facilitate and support manufacturing and QA/QC process improvements within single or across multiple sites for manufacture of clinical supplies.
- ! Assure efficient and effective resolution of critical product quality/compliance issues, identified internally or by customers, involving clinical supplies.
- ! Define and maintain product compliance/robustness profile for pharma new products in development. Responsible for risk mitigation and communication of any new product risks while under development to management and sites.
- ! Support and facilitate technology transfer (process, methods etc.)

WYETH RESEARCH, Collegeville, PA $
Associate Director, CMC, Global Regulatory Affairs (07/06 – 11/07) $
Sr. Manager, CMC, Worldwide Regulatory Affairs (11/04 – 06/06) $

Responsibilities included:

- ! Coordinated the CMC Pilot Program participation and developed/executed the strategy for the regulatory filings across the globe for a sustained release dosage form
    - ! Authored, Submitted and managed the global filings of 2 New Drug Applications globally. Successfully filed and obtained approval of marketing authorizations globally.
    - ! Coordinated and managed Type 2 meetings (approximately 12 in number) with the FDA during the IND and NDA stages of the 2 NDA's
    - ! Led the Real time release testing technical team and developed the regulatory strategy for Real Time Release (RTR) Implementation at Wyeth, Served as the Wyeth regulatory strategist/spokesperson with regulatory boards of health. Authored, submitted and obtained approval of a comparability protocol for the implementation of real time release in the US.
        - ! Development, approval and implementation of model maintenance procedures for all the in-process techniques with contingencies for failure modes leading to a robust quality approach for implementation of RtR.
        - ! Development of approach facilitating alternative approach for dissolution testing using a mechanistic understanding enabling RtRt for dissolution for an extended release drug product.

    - ! Lead Wyeth contact during the pre-approval inspections and the pre-operational visit (for RTR) of the manufacturing site.
    - ! Led the team in the development of systems to support the QbD implementation and later RTR implementation at the manufacturing site
- ! Develop CMC regulatory strategy for 10 inflammation and 3 neuroscience products, filed approximately 15 IND's and a number of amendments to support the entire portfolio of products.
- ! Key member of European Product Conformance team. Developed strategy to streamline review of all Wyeth MA's approved in Europe and file variations to harmonize them.
- ! Developed the CMC template for the streamlined filing of Analytical methods and validation reports.
- ! Represented regulatory on many inter-disciplinary teams; formulated an initial recommendation for regulatory strategy and lead teams whenever necessary.
- ! Actively interacted with agencies and affiliates on a frequent basis to ensure good communication.

ABBOTT LABORATORIES, North Chicago, IL $
Research Investigator Analytical Chemist (04/02 – 11/04) $
Senior Research Scientist (04/00 – 04/02) $
Research Scientist (05/97 – 04/00) $

Responsibilities included:
- ! Evaluating new technologies to streamline the analytical process and increase efficiency
- ! Communicating effectively with team members and developing strategies to achieve both project and organization goals in a timely manner.
- ! Scientific/Technical: Qualification, development and validation of methods using modern analytical techniques. Transfer of analytical methods to laboratories worldwide.
- ! Demonstrating and applying cross-functional knowledge. Lead teams in investigations to resolve complex scientific and technical issues.
- ! In collaboration with key personnel, identify, synthesize and characterize solid state forms of developmental compounds using a multitude of techniques and understand their interrelationships. Develop methods for characterization of the undesired crystal forms in drug substances and drug products
- ! Supervision and mentoring of junior staff toward the achievement of corporate goals with technical leadership, managerial supervision, feedback and coaching.
- ! Author CMC sections of global filings and collaborate with team members in planning the submission of drug IND's, NDA's etc. Respond to requests from regulatory agencies on CMC issues in a timely manner. Lead preapproval inspection readiness activities.
- ! GMP Documentation and Compliance: Maintain conformance with GMP, write/review/approve GMP documents (specifications, stability study protocols, exception documents etc.), operating procedures etc.

Addendum $

Honors $

1. $**"Wyeth President's Achieving Excellence Team Award,"**- in recognition of the flawless execution of QbD/QRM principles during the development of HKI-272 and changing the paradigm of TD&T – December 2008.
2. $**"Regulatory Sciences Recognition Award – AAPS"** – in recognition of outstanding service to the regulatory sciences section of AAPS – November 2006.
3. $**"DVS-233 Major Depressive Disorder Team Award,"** for the development and submission of the DVS-233 NDA for MDD, February 2006.
4. $**"DVS Quality by Design Team Award,"** for development and implementation of the quality by design approach for DVS-233, February 2006.
5. $**"Recognition Award from AAPS,"** in recognition of contributions and dedication to the APQ open forum, Oct 2003.
6. $"**Certificate of Excellence**," for outstanding performance and lasting contribution to the UPRIMA GPRD Development Team, 2003.
7. $"**Spot Award from TAP**," for an outstanding job on the Apomorphine LOD Investigation, 2003.
8. $"**Quality Spot Award**," For Extraordinary Quality in Apomorphine Code Material 2R Testing Support, 2002.
9. $"**Quality Spot Award**," For Extraordinary Quality in Outstanding Laboratory Support for UPRIMA AI, 2001.
10. "**Quality Spot Award**," For Extraordinary Quality in UPRIMA Launch and Validation Testing – AI, 2001.
11. Member, **Deans Graduate Student Advisory Council**, 1996-1997.
12. Recipient of the **Outstanding Poster Award** at the **Graduate Research Day**, College of Pharmacy, University of Georgia (Athens, GA, Oct 1996).
13. Recipient of **APQ Graduate Symposium Fellowship** for the year 1996.
14. Recipient of **the Outstanding Poster Award** at the Southeastern Regional AAPS meeting (Research Triangle Park, NC, Jun 1996).
15. Northeast Georgia section American Chemical Society's **Outstanding Chemistry Graduate Student at the University of Georgia** for the year 1996.

Publications $

1. ! D.T. King, T.G. Venkateshwaran and J.T. Stewart, "HPLC determination of a Vincristine, Doxorubicin and Ondansetron Mixture in 0.9% Sodium Chloride injection," **Journal of Liquid Chromatography**, 17(6), 1399-1411 (1994).
2. ! T.G. Venkateshwaran, D.T. King and J.T. Stewart, "HPLC determination of a Metoclopramide Ondansetron mixture in 0.9% Sodium Chloride injection," ***Journal of Liquid Chromatography,*** 18(1), 117-126 (1995).
3. ! T.G. Venkateshwaran and J.T. Stewart, "*HPLC determination of Morphine-Hydromorphone- Bupivacaine and Morphine-Hydromorphone-Tetracaine mixtures in 0.9% Sodium Chloride injection,"* ***Journal of Liquid Chromatography,*** 18(3), 565-578 (1995).
4. ! T.G. Venkateshwaran, D.T. King and J.T. Stewart, "*HPLC determination of Ondansetron - Atropine and Ondansetron - Glycopyrrolate mixtures in 0.9% Sodium Chloride injection*," ***Journal of Liquid Chromatography***, 18(13), 2647-2659 (1995).
5. ! T.G. Venkateshwaran and J.T. Stewart, "*Determination of Metronidazole in vaginal tissue by HPLC with Solid Phase Extraction,*" ***Journal of Chromatography - Biomedical Applications***, 672, 300-304 (1995).
6. ! T.G. Venkateshwaran, D.T. King and J.T. Stewart, "*HPLC determination of Morphine- Ondansetron and Meperidine-Ondansetron mixtures in 0.9% Sodium Chloride injection*," ***Journal of Liquid Chromatography and Related Technologies***, 19 (8), 1329-1338 (1996).
7. ! D.T. King, J.T. Stewart and T.G. Venkateshwaran, "HPLC *determination of Propofol-Thiopental Sodium and Propofol-Ondansetron mixtures," **Journal of Liquid Chromatography and Related Technologies***, 19 (14), 2285-2294 (1996).
8. ! J.T. Stewart, Janet Fox, Flynn Warren, T.G. Venkateshwaran, Garrat W. Ponder and D.T. King, "*Stability of Ondansetron Hydrochloride with Doxorubicin - Dacarbazine and Doxorubicin - Vincristine in elastomeric portable infusion devices and PVC bags," **American Journal Health System Pharmacy,*** 54, 915-920, (1997).
9. ! T.G. Venkateshwaran, D.T. King and J.T. Stewart, "*HPLC determinations of Ondasetron with Selected medications in 0.9% sodium chloride injection USP," **Journal of Liquid Chromatography and Related Technologies***, 19 (20), 3355-3367 (1996).
10. J.T. Stewart, Janet Fox, Flynn Warren, T.G. Venkateshwaran and D.T. King, *"Stability of Ondansetron Hydrochloride with perioperative mixtures in PVC bags,"* submitted to the ***American Journal of Hospital Pharmacy,*** Jun 1996.
11. T.G. Venkateshwaran, J.T. Stewart, R.T. Bishop, J. A. deHaseth and M.G. Bartlett, *"Solution conformation of model peptides with the use of particle beam LC/FT-IR spectrometry and electrospray mass spectrometry,"* ***Journal of Pharmaceutical and Biomedical Analysis***, 17 (1998) 57-67

12. T.G. Venkateshwaran, J.T. Stewart, J. A. deHaseth and M.G. Bartlett, *"Solution conformation of model polypeptides with the use of particle beam LC/FT-IR spectrometry and electrospray mass spectrometry,"* ***Journal of Pharmaceutical and Biomedical Analysis***, 19 (5) (1999), 709-723.
13. T.G. Venkateshwaran, J.T. Stewart, C.R. McCurdy and J.W. Beach, "*Enantiomeric separation of lobeline analogs using capillary electrophoresis: Effect of chiral additives, organic modifiers and pH,"* ***Electrophoresis***, 20 (1999), 212-218.
14. J.T. Stewart, M. Siluveru, W.J. Bachman, T.G. Venkateshwaran, D.C. Delinsky and B.K. Matuszewski, "*Enhanced HPLC Determination of Selected Drugs in Serum Using Post-Column Irradiation and Fluorescence/Electrochemical detection,"* in ***Drug-development Assay Approaches Including Molecular Imprinting and Biomarkers (Vol. 25, Methodological Surveys in Bioanalysis of Drugs). Ed. E. Reid, H.H. Hill, and I.D. Wilson, Royal Soc. of Chemistry - New York Agent: Springer***, 170-176 (1998).
15. James T. Stewart, Flynn W. Warren, Deanne T. King, T.G. Venkateshwaran, and Janet T. Fox*, "Stability of Ondansetron Hydrochloride and 12 Medications in Plastic Syringes,"* ***Am. J. Health-Syst Pharm****, 55(1998) 2628-2634*.
16. Thirunellai G. Venkateshwaran, John Levins, and Stephen P. Simmons, *"Key Aspects to a Successful Implementation of Process Analytical Technologies (PAT) in Pharmaceutical Manufacturing,"* ***European Pharmaceuticals Review*** (Issue 5, 2008).
17. Graham D. Cook, Thirunellai G. Venkateshwaran, and Stephen P. Simmons**,** *"Making Quality by Design part of Wyeth's DNA,"* ***World Pharmaceutical Frontiers***, 2009.
18. Thirunellai G. Venkteshwaran, Stephen P.Simmons, Nirdosh Jagota, Donald G. Esherick, and Patricia F. Mann, "*Global Regulatory Submissions for QbD – Wyeth's Experience in the CMC Pilot Program,"* ***Pharmaceutical Technology****, 33(10),* pp 96-102 (2009).
19. Shailesh Singh, Thirunellai G. Venkateshwaran, Arwinder Nagi and Stephen P. Simmons*, "Oral Controlled Drug Delivery: Quality By Design approach to Drug Development,"* in ***Oral controlled release formulation design and drug delivery: theory to practice / edited by Hong Wen, Kinam Park, Wiley Publishers, 2010.***
20. Yong Cui, King Chuang, Cadapakam J. Venkatramani, Thirunellai G. Venkateshwaran, Gregory Gallegos, Sueanne Lee and Minli Xie, ***"Variable selection in multivariate modeling of drug product formula and manufacturing process"*** accepted for publication **–** *Journal of Pharmaceutical Sciences (08/2012).*

Presentations $

1. ! D.T. King, T.G. Venkateshwaran and J.T. Stewart, "*HPLC determination of a Vincristine, Doxorubicin and Ondansetron Mixture in 0.9% Sodium Chloride injection*," ***South Eastern Regional Meeting of the American Association of Pharmaceutical Scientists (SEAAPS),"*** Research Triangle Park, NC, Apr 1993.
2. ! D.T. King, T.G. Venkateshwaran and J.T. Stewart, "*HPLC determination of a Vincristine, Doxorubicin and Ondansetron Mixture in 0.9% Sodium Chloride injection*," ***National Meeting of the American Association of Pharmaceutical Scientists (AAPS)***. Orlando, FL, Nov 1993.
3. ! D.T. King, J.T. Stewart, F.W. Warren and T.G. Venkateshwaran, "*Ondansetron Stability with Vincristine and Doxorubicin in 0.9% Sodium Chloride injection,*" ***28th Annual American Society of Hospital Pharmacists (ASHP) Midyear Clinical Meeting,*** Atlanta, GA, Dec 1993.
4. ! T.G. Venkateshwaran and J.T. Stewart, "*A Sensitive Method for the determination of Metronidazole in vaginal tissue," **South Eastern regional AAPS***, Durham, NC, Apr 1994.
5. ! T.G. Venkateshwaran, Bradley R. Simmons, Madhusudhan Siluveru and J.T. Stewart, "*A Sensitive Method for the determination of Metronidazole in vaginal tissue," **National AAPS***, San Diego,CA, Nov 1994.
6. ! J.T.Stewart, D.T.King, F.W.Warren and T.G.Venkateshwaran, *"Compatibility and Stability studies of Perioperative medication mixtures containing Ondansetron with selected drugs," 29th **Annual ASHP Midyear Clinical Meeting***, Miami Beach, FL, Dec 1994.
7. ! J.T.Stewart, D.T.King, F.W.Warren and T.G.Venkateshwaran, *"Compatibility and Stability studies of Perioperative medication mixtures containing Ondansetron with selected drugs," **29th Annual ASHP Midyear Clinical Meeting***, Las Vegas, NV, Dec 1995.
8. ! T.G. Venkateshwaran and J.T. Stewart, "*HPLC determination of Morphine-Hydromorphone- Bupivacaine and Morphine-Hydromorphone-Tetracaine mixtures in 0.9% Sodium Chloride injection," 6th **International Symposium on Pharmaceutical and Biomedical Analysis***, St. Louis, MO, Apr 1995.
9. ! T.G. Venkateshwaran and J.T. Stewart, *"HPLC of a synthetic octapeptide," **South Eastern Regional Meeting of the American Association of Pharmaceutical Scientists.*** Research Triangle Park, NC, Jun 1995.
10. T.G. Venkateshwaran, J.T. Stewart, J.A. deHaseth, Randy Bishop and V.E. Turula, *"HPLC- FTIR, A new approach to study the stability of peptides in parenteral solutions," **International symposium of peptides, proteins and polynucleotides '95***, Boston, MA, Nov 1995.

11. T.G. Venkateshwaran, J.A. deHaseth, Randy Bishop and V.E. Turula,*" Secondary structure of unfolded proteins by Reversed phase HPLC particle beam LC/FTIR spectrometry and capillary zone electrophoresis," **International symposium of peptides, proteins and polynucleotides '95***, Boston, MA, Nov 1995.
12. T.G.Venkateshwaran, J.T.Stewart and D.T.King, "*HPLC determination of Ondansetron - Morphine and Ondansetron-Meperidine mixtures in 0.9% Sodium Chloride injection,*" ***National AAPS***, Miami, FL, Nov 1995.
13. T.G. Venkateshwaran, J.T. Stewart, J.A. dehaseth, V.E. Turula and R.T. Bishop, "Secondary *structure studies of peptides/polypeptides using LC/FTIR: A method to estimate the stability of peptides/polypeptides in parenteral solutions," **20th, International Symposium on High Performance Liquid Phase separations (HPLC '96)***, SanFrancisco, CA, Jun 1996.
14. T.G. Venkateshwaran, J.T. Stewart, Christopher R. McCurdy and J.W. Beach, *"Enantiomeric separation of lobeline analogs using Capillary Electrophoresis Effect of cyclodextrin additives," **SouthEastern Regional Meeting of the American Association of Pharmaceutical Scientists (AAPS)***, Research Triangle Park, NC, Jun 1996.
15. T.G. Venkateshwaran, David Delinsky and J.T. Stewart, *"Determination of Oxymorphone in serum using HPLC, Solid Phase Extraction and Standard Addition," **SouthEastern Regional Meeting of the American Association of Pharmaceutical Scientists (AAPS)***, Research Triangle Park, NC, Jun 1996.
16. T.G. Venkateshwaran, J.T. Stewart and J.A. deHaseth, *"Particle Beam LC-IR Spectroscopy*: *A novel technique to investigate the secondary structural stability of peptides in solution," **SouthEastern Regional Meeting of the American Association of Pharmaceutical Scientists,*** Research Triangle Park, NC, Jun 1996.
17. T.G. Venkateshwaran, D.T. King and J.T. Stewart, "*HPLC determinations of Ondansetron with selected medications in 0.9% Sodium Chloride injection USP," **Annual meeting of the American Chemical Society***, Orlando, FL, Aug 1996.
18. T.G. Venkateshwaran, D.C. Delinsky and J.T. Stewart, *"Determination of Oxymorphone in serum using HPLC, Solid Phase Extraction and Standard Addition," **National AAPS***, Seattle, November 1996.
19. T.G. Venkateshwaran, J.T. Stewart, M.G. Bartlett, R.T. Bishop and J.A. deHaseth, "*Particle Beam LC-IR spectroscopy, Electrospray LC-MS as tools for the investigation of conformational stabilities of peptides/proteins in solution," **National AAPS***, Seattle, November 1996.
20. T.G. Venkateshwaran, J.T. Stewart, Christopher R. McCurdy and J.W. Beach, *"Enantiomeric separation of lobeline analogs using Capillary Electrophoresis: Effect of cyclodextrin additives," **Graduate Research Day,*** UGA, Oct 1996.
21. T.G. Venkateshwaran, David Delinsky and J.T. Stewart, *"Determination of Oxymorphone in serum using HPLC, Solid Phase Extraction and Standard Addition," **Graduate Research Day,*** UGA, Oct 1996.

22. T.G. Venkateshwaran, J.T. Stewart and J.A. deHaseth, *"Particle Beam LC-IR Spectroscopy* : *A novel technique to investigate the secondary structural stability of peptides in solution ,"* ***Graduate Research Day,*** UGA, Oct 1996

23. T.G. Venkateshwaran, J.T. Stewart, Christopher R. McCurdy and Joseph W. Beach, *"Chiral Separation of Lobeline analogs using High Performance Capillary Electrophoresis and derivatized cyclodextrins as buffer additives,"* presented at the ***Annual meeting of the American Chemical Society,*** San Francisco, April 1997.

24. R.T. Bishop, T.G. Venkateshwaran, J.T. Stewart, M.G. Bartlett and J.A. deHaseth,*"Conformational effects on reversed phase chromatography of RNase A with Electrospray LC-MS and Particle beam LC/FT-IR spectrometry , "* ***8th International Symposium on Pharmaceutical and Biomedical Analysis***, Orlando, May 1997.

25. J.T. Stewart, M. Siluveru, W.J. Bachman, T.G. Venkateshwaran, D.C. Delinsky and B.K. Matuszewski, "*Enhanced HPLC Determination of Selected Drugs in Serum Using Post-Column Irradiation and Fluorescence/Electrochemical detection,"* ***International Symposium, on The Bioanalysis of Drugs***, London, June 1997.

26. Randall T. Bishop, T.G. Venkateshwaran, James A. de Haseth, J.T. Stewart, M.G. Bartlett, "Protein Conformational Analysis under Reversed Phase HPLC Conditions by Particle Beam LC/FT-IR Spectrometry and Electrospray LC/MS", ***11th International Conference of Fourier Transform Spectroscopy***, Athens, GA, 1997.

27. T.G. Venkateshwaran, D.C. Delinsky, H. Patel and J.T. Stewart, *"Reversed-Phase HPLC Perioperative Mixtures using Underivatized Silica Columns and Aqueous-Organic Mobile Phases,"* ***National AAPS,*** New Orleans, November 1999**.**

28. B. Kuckkan, R.L Hertzler, and T.G. Venkateshwaran, "*Enantiomeric Separation of NS-49 Enantiomers using Chiral HPLC and Capillary Electrophoresis,"* ***Abbott Corporate Technology Exchange*****,** June 1999.

29. K .Sealey, M .Trust, P. Redfern, L. Whent, T.G. Venkateshwaran, C. Havrilla, Z. Iqbal, D. Banick, and B. Pierson, *" Derivatization of EDTA to Optimize UV Detection and Quantification by HPLC in a Novel Drug Product,"* ***Abbott Corporate Technology Exchange***, June 2001.

30. J. Doddi, W. Dziki, and T.G. Venkateshwaran, *"Rapid Identification of an Active Pharmaceutical Ingredient (API) in Low Drug Load Sub-Lingual Tablets by FT-IR Spectroscopy,"* ***Abbott Corporate Technology Exchange***, June 2001.

31. Marsden, S .Hollis,. R. Henry, S. Spanton, G.N. Subbarao, and T.G. Venkateshwaran, *"Polymorphism of ABT-198,"* ***Abbott Corporate Technology Exchange***, June 2001.

32. T.G. Venkateshwaran, Z. Iqbal, D. Banick, B. Nichols, W. Dziki, N. Chambers, and R. Henry, *"Hygroscopicity of Apomorphine Hydrochloride,"* ***Abbott Corporate Technology Exchange***, June 2001.

33. T.G. Venkateshwaran, Z. Iqbal, D. Banick, B. Nichols, W. Dziki, N. Chambers, and R. Henry, *"Hygroscopicity of an Active Pharmaceutical Ingredient used for the treatment of Erectile Dysfunction,"* ***Annual AAPS Meeting***, Denver, October 2001.

34. T.G. Venkateshwaran, D.W. Banick, and T.E. Grosch, *"A Reversed Phase Method for the Determination of the Chiral Purity of R (-) Apomorphine HCl in Apomorphine HCl Tablets, SL,"* ***Annual AAPS Meeting***, Toronto, November 2002.

35. T.G. Venkateshwaran, D.W. Banick, and T.E. Grosch, "*A Reversed Phase Method for the Determination of the Chiral Purity of R (-) Apomorphine HCl in Apomorphine HCl Tablets, SL*," ***Abbott Corporate Technology Exchange*****,** Abbott Park, October 2003.

36. T.G. Venkateshwaran, R.L. Hertzler and T. J. Gray, "*A Sensitive Normal Phase HPLC Method for the Determination of A-631972, the undesired enantiomer of A-358239.74, in the Active Pharmaceutical Ingredient,"* ***Abbott Corporate Technology Exchange*****,** Abbott Park, October 2003.

37. T.G. Venkateshwaran, J.Doddi and W. Dziki, "*Rapid Identification of an Active Pharmaceutical Ingredient (API), in Low Drug Load Sub-Lingual Tablets, by FT-IR Spectroscopy,"* ***Annual Meeting of the American Association of Pharmaceutical Scientists*****,** Salt Lake City, October 2003.

38. T.G. Venkateshwaran, T.J. Gray and R.L. Hertzler, *"Determination of the Chiral Impurity (Undesired Enantiomer) in ABT-239 Drug Substance using Normal Phase HPLC,"* ***Annual Meeting of the American Association of Pharmaceutical Scientists*****,** Salt Lake City, October 2003.

39. T.G. Venkateshwaran, *"Determination of the Undesired Enantiomer in A-422894.112 Drug Substance using High Performance Capillary Electrophoresis,"* ***Annual Meeting of the American Association of Pharmaceutical Scientists*****,** Baltimore, November 2004.

40. T.G. Venkateshwaran, ***"Impurity Control and Regulation in Drug Substances and Drug Products: An Overview,"*** *Barnett International Conference on* ***"Control of Impurities, Degradants and Solvents in Drug Substances and Drug Products,"*** Philadelphia, June 2005.

41. T.G. Venkateshwaran, ***"Developing Drug Product Stability Programs according to FDA/ICH Guidelines,"*** ICI Conference on ***"Stability Programs – New Approaches to Test, Analyze and Document Data for Improved Program Design and Global Compliance,"*** June 2006.

42. T.G. Venkateshwaran, ***"Regulatory Aspects of Low-Level Impurities – What Does it mean,"*** *at the Roundtable on Low Level Impurities – Scientific and Regulatory Challenges,* ***at the Annual Meeting of the American Association of Pharmaceutical Scientists***, San Antonio, October 2006.

43. T.G. Venkateshwaran, ***"Quality by Design – Industrial Perspective,"*** keynote address at the ***Pharmaceutical Technology – Annual Conference (2007)***, Philadelphia, July 2007.

44. T.G. Venkateshwaran, ***"ICH Q8- Pharmaceutical Development,"*** Quality session at the ***Pharmaceutical Technology – Annual Conference (2007)***, Philadelphia, July 2007.

45. T.G. Venkateshwaran, ***"ICH Q8 and Q9 – Impact on Stability Programs, a Review,"*** at the ***AAPS Workshop on Pharmaceutical Stability Testing to Support Global Markets***, Bethesda, September 2007.

46. T.G. Venkateshwaran, P. Nambiar and N.Jagota, ***"Regulatory Pathway for Managing Drug Product CMC Changes during Development and Post-Approval,"*** at the ***Annual Meeting of the American Association of Pharmaceutical Scientists***, San Diego, November 2007.

47. T.G.Venkateshwaran, ***"Operationalization of Design Space," Regulatory Science Open Forum on Establishment and Maintenance of Design Space",*** at the ***Annual Meeting of the American Association of Pharmaceutical Scientists***, Atlanta, November 2008.

48. T.G. Venkateshwaran, ***"Quality by Design – An Industrial Perspective,"*** at the ***FDA Level III Drug Investigator Certification Course,*** Silverspring, Maryland, December 2008.

49. T.G. Venkateshwaran, ***"Quality by Design – An Industrial Perspective,"*** at ***DIA's third Annual Conference on Drug Discovery and Clinical Development in India-Scientific, Regulatory and Social Frontiers,*** Mumbai, February 2009.

50. T.G. Venkateshwaran, ***"Enabling Real time Release – Practical Challenges and Opportunities in the Implementation of Real Time Release,"*** at ***Pharmaceutical Technology Annual Conference 2009***, Philadelphia, August 2009.

51. S.Singh, T.G. Venkateshwaran, N.Jagota and R.Saunders, "***Criticality Assessment-Identification of Critical Quality Attributes (CQA) & Critical Process Parameter (CPP) for a MR Dosage form (DP)," at the Annual Meeting of the American Association of Pharmaceutical Scientists***, Los Angeles, November 2009

52. T.G. Venkateshwaran, ***"Development of Quality Systems for Real Time Release – Practical Challenges and Opportunities,"*** at ***PDA Annual Meeting –*** 2010, Orlando, March 2010.

53. T.G. Venkateshwaran, ***"Quality by Design – An Industrial Perspective,"*** at the ***FDA Level III Drug Investigator Certification Course,*** Rockville, Maryland, March 2010.

54. T.G.Venkateshwaran and N.K.Jagota, ***"Building Quality During Pharmaceutical Development and Manufacturing," at Interphex 2010***, New York, April 2010.

55. T.G. Venkateshwaran, ***"Presenting PAT and QbD to the FDA,"*** at ***International Federation for Process Analytical Chemistry (IPFAC) San Juan, 2010 Meeting, San Juan, Puerto Rico,*** June 2010.

56. T.G. Venkateshwaran, ***"Quality by Design – An Industrial Perspective," at the FDA Level III Drug Investigator Certification Course***, Rockville, Maryland, December 2010.

57. T.G. Venkateshwaran ***"Quality Systems for Real Time Release Testing – Evolution or Revolution" DIA Workshop on Translating Science into Regulatory Submissions,*** Washington DC, February, 2011.

58. T.G. Venkateshwaran, ***"Quality by Design – An Industrial Perspective,"*** at the ***FDA Level III Drug Investigator Certification Course,*** Rockville, Maryland, June 2011.

59. T.G. Venkateshwaran, ***"Corrective and Preventative Actions – CAPA," at the ISPE Workshop – From Basic GMP to Q10 Pharmaceutical Quality System***, Mumbai, India, October 2011.

60. T.G. Venkateshwaran, ***"Process Validation in the ICHQ8, Q9 and Q10 realm- What does it mean?" at the ISPE Workshop – From Basic GMP to Q10 Pharmaceutical Quality System***, Mumbai, India, October 2011.

61. T.G. Venkateshwaran, *"**Implementation of Continuous Manufacturing in the Pharmaceutical Industry: Challenges and Opportunities," at the Parenteral Drug Association Annual Meeting,*** Baltimore, September 2012

62. T.G Venkateshwaran, ***"Enhanced Control Strategy for Biologics," at the APQ Open Forum on "Control Strategy – Development, Implementation and Regulatory Expectations",*** at the ***Annual Meeting of the American Association of Pharmaceutical Scientists, San Antonio, November 2013.***

63. T.G. Venkateshwaran, ***"Industry Example – Enhanced Control Strategy for Biologics," at the International Forum for Process Analytical Chemistry (IFPAC) Annual Meeting***, Washington DC, January 2014

64. T.G. Venkateshwaran, ***"Combination Products – Current Regulatory Landscape," at the 42nd International GMP Conference,*** Athens, GA, March 2018

65. T.G. Venkateshwaran, ***"CMC Enablers in the Accelerated Approval of Biologics: Industry Perspective," 2018 Drug Information Association (DIA) Annual Meeting,*** Boston, June 2018.

66. T.G.Venkateshwaran and Lucy Chang, ***"Regulatory Opportunities and Hurdles in New Technology Development for Biopharmaceuticals," 2018 Drug Information Association (DIA) Annual Meeting,*** Boston, June 2018.

67. T.G. Venkateshwaran, "***Developing Continuous Manufacturing for Biologicals: Technical and Regualtory Considerations," 2019 Global Bio Conference,*** Seoul, South Korea, June 2019.

68. T.G.Venkateshwaran, ***"Moving Heaven and Earth: The Manufacturing Commercialization of a Cancer Therapy and What came After," 2019 Drug Information Association (DIA) Advancing CMC Workshop,*** Basel, Switzerland, November 2019.

Affiliations

Chair "CMC Focus Group" – AAPS (2007 – 2011)
Secretary, Vice Chair , Chair elect, and Chair (2011-2014)- Regulatory Sciences Section, American Association of Pharmaceutical Scientists
Member, Organizing Committee, CMC Forum and Well Characterized Biotechnology Products (WCBP) - 2018
Committee member – ISPE Quality and Compliance Technical Documentation