# Ajit Dhavle Pharm.D, MBA

**VP of Health IT, Audits & Life Sciences**

**Quandary Peak Research**
Washington D.C.

[quandarypeak.com/ajit](quandarypeak.com/ajit)

703-665-6421 DIRECT
540-327-5437 MOBILE
[ajit@quandarypeak.com](ajit@quandarypeak.com)

Dr. Dhavle is a Partner at Quandary Peak Research. He oversees a team of Health Informatics Experts to provide Strategy, Management, Product Management, Software Development Life Cycle (SDLC), Safety, Compliance, and Engineering Consulting and Audit services to both Government and Commercial entities.

## Summary

Innovative healthcare technology leader and chief problem solver:

- Consulting clients include major Digital Health companies, EHR vendors, Pharmacy vendors, Pharmaceutical manufacturers, Federally Funded R&D Centers, Health and Human Services (HHS), U.S. Department of Justice, and the ONC (Office of National Coordinator for Health IT) on matters involving Strategy, Health IT Software Development Lifecycle, Software Quality, Standards, Usability, Patient Safety Risk Compliance and Best Practices, Regulatory affairs, and Standards implementation.

- Created the first nation-wide e-Prescribing Continuous Quality Improvement Program to measure, monitor and improve the quality of e-prescriptions in the U.S.

- Built and successfully deployed Adviva Health, a SaaS prescription medication history reconciliation and analytics platform, to streamline the user EHR medication experience.

- Track record of successful implementations of large-scale HIT programs and solutions that introduce efficiencies, drive customer satisfaction and growth, and enhance revenues.

## Areas of Expertise

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|---|---|---|
| Patient Safety | Management Consulting | Prescriber & Pharmacy Workflows |
| Business Development | Process Improvement | E-Prior Authorization (e-PA) |
| Innovation | Operational Improvement | FDA - REMS |
| Product Strategy | Healthcare Systems Integration | Clinical Interoperability |
| Program Management | Data Analytics | Clinical Terminology |
| Revenue Growth | Healthcare Tech Optimization | Litigation / Malpractice Consulting |
| Pharmacy Management Systems | Health Information Exchange | HIT standards |
| Electronic Prescribing (e-Rx) | E-Medication History | Formulary and Benefit Eligibility |

## Employment

**Vice President, Health IT, Audit & Life Sciences**

Quandary Peak Research | Washington D.C. | Feb 2021–Present

- – Directing a practice group of 15 Health IT Subject Matter Experts to provide consulting services in areas related to strategy, product strategy and design, product management, software regulatory compliance, quality and risk management systems, and best practices for managing risk and safety in IT.
- – Clients include Health IT and Digital Health organizations, Healthcare systems, Pharma Service Providers, EHR and Pharmacy vendors, and Federal agencies.
- – Provide legal expert witness services for cases involving Health IT software.
- – Led the eClinicalWorks Software Quality Oversight Organization - a first of kind 5-year Corporate Integrity Agreement administered jointly by the Office of the National Coordinator for Health IT (ONC) & the Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS).

## Principal Managing Partner
Rchemie International, LLC | Aug 2017–Feb 2021

- – Provide independent consulting services to Health IT software vendors and Federal agencies
- – Notable Government audits and software quality compliance consulting projects, include:
    - ○ Certified Health IT Electronic Health Record Vendor - (CLIENT CONFIDENTIAL)
      Consulted regarding Meaningful Use compliance and regulatory matters.
    - ○ Certified Health IT Electronic Health Record Vendor - (CLIENT CONFIDENTIAL)
      Performed gap analysis and delivered recommendations to help improve company's compliance with CEHRT regulations.
    - ○ Certified Health IT Electronic Health Record Vendor - (CLIENT CONFIDENTIAL) – review of issue tracking records and software artifacts to identify potential regulatory guidance and provide best practice recommendation solutions.
    - ○ FDA Risk Evaluation and Mitigation Strategy (REMS) -(CLIENT CONFIDENTIAL)
      Performing independent data quality, process and systems review for a major shared REMS program including 21 CFR Part 11 compliance review, review of software documentation, program business and metric requirements, quality assurance procedures, annual report and submissions, and assisting with responses to FDA inquiries.
    - ○ eClinicalWorks, LLC and the Office of the Inspector General of HHS – Member of the Software Quality Oversight Organization (SQOO) - serving as an independent audit and oversight organization covering technical, clinical and quality review of EHR software and development processes as it relates to o patient safety and regulatory compliance.

## Founder CEO
Adviva Health, Inc | Sept 2017–Present

- – The Adviva Health platform is a fully integrated and one-stop-shop patient electronic medication history analytics platform that arms providers with quickly accessible and actionable patient medication data intelligence to help drive better health care decisions and resulting health outcomes.
- – Developed, integrated, and deployed the embedded SAAS platform solution within a Meaningful Use Certified EHR with excellent feedback from practice staff and providers.

## Vice President – Clinical Quality
Surescripts | July 2014–Dec 2016

- – Responsible for corporate Clinical Quality, Patient Safety, and Quality Research initiatives.

- Forge partnerships with key industry leaders, patient safety experts, vendors, and agencies to ensure appreciation for and alignment with corporate quality programs.
- Notable Projects:
  - Created the national E-prescription Quality Blueprint plan to standardize, codify and improve quality of all e-prescribing transactions; transitioned to the Product Innovation Team responsible for execution and served as the SME-senior advisor.
  - Lead team that engages 700+ EHR & 100+ pharmacy vendor accounts to drive network-wide quality improvements and delivered year-over-year network-wide e-prescribing quality improvements by over 35%.
  - Lead peer-reviewed research to investigate current e-medication management and e-prescribing gaps, identify solutions, and drive industry-wide best practices.
  - Lead industry-wide e-medication management and e-prescribing product enhancement and quality improvement efforts to drive growth and improve end-user satisfaction.
  - Conceptualized, launched and operated the first national Pharmacy e-Messaging and e-Medication History Continuous Quality Improvement program initiatives.

## Director – Clinical Quality
Surescripts | Sept 2010–June 2014

- Responsible for corporate Clinical Quality and Patient Safety initiatives.
- Demonstrated year-over-year network-wide quality improvements and exceeded target goals on all key transactional quality metrics by 30% every year.
- Acted as liaison with external organizations and thought leaders on all e-prescribing quality matters.
- Notable Projects:
  - Conceptualized and created first-of-its-kind E-Prescribing Continuous Clinical Quality Improvement Program to measure, monitor, and improve quality of US e-prescriptions.
  - Built and led a team of clinicians and quality specialists to drive e-prescribing changes and quality improvements across all connected vendors.
  - Developed the Quality Support team to investigate all end user-reported quality events and established an internal protocol to ensure complete resolution.
  - Implemented the annual Surescripts White Coat of Quality award program to recognize and award EHR vendors that demonstrate e-prescribing quality improvements – coveted national recognition.

## Senior Manager – Quality
Surescripts | May 2009–Sept 2010

- Responsible for corporate Patient Safety and Clinical Quality initiatives.
- Notable Projects:
  - Design e-prescription quality rating system to analyze potential safety issues and to conduct vendor reviews aimed at improving quality and patient safety.
  - Co-invented (patent pending) and directed technical implementation of a Quality Engine to rate quality of e-prescriptions and detect patient safety issues to drive quality improvements.
  - Conducted provider office site visits to analyze e-prescribing meaningful usage; findings led to creation of a new mail order e-prescription growth strategic initiative and revenue growth.

### Senior Manager – Clinical Practice Integration
Surescripts | Jan 2008–May 2009

- Served as expert consultant to help clients and federal and state agencies to create and deploy e-prescribing and Health IT adoption and utilization strategies.
- Notable Projects:
    - Developed and implemented a vendor engagement strategy that led to addition of 1400+ new network prescribers resulting in instant net increase in billable volume and revenue.
    - Piloted e-prescribing projects in partnership with government agencies and vendors; one project resulted in 33% growth in billable e-prescription transaction volume in a three-month period.
    - Managed and executed a study analysis to understand EHR/e-prescribing adoption and utilization patterns among physicians; led to creation of new marketing campaigns and network-wide growth.

### Manager – Clinical Practice Integration
Surescripts | Jan 2007–Dec 2008

- Analyzed provider and pharmacy e-prescribing applications to understand current deployments; created new certification requirements and best practices to optimize quality.
- Notable Projects:
    - Created the product strategy and business case for Continuity of Care Record (CCR) e-messaging, which resulted in a net new product offering and revenue stream.
    - Successfully managed the first Surescripts Electronic Healthcare Network Accreditation Commission (EHNAC) accreditation.
    - Implemented the "Large Clinic" project and subsequent program to study e-prescribing deployment and grow utilization in large healthcare systems.

### Product Manager
Surescripts | Aug 2005–Dec 2006

- Managed the core Surescripts prescription routing product and experienced triple-digit growth.
- Authored external implementation and certification guides and network requirements.
- Coordinated and led end-user facing e-prescribing Experience Demonstrations with EHR and pharmacy system vendors at multiple pharmacy and prescriber conferences to promote e-prescribing adoption and utilization.
- Notable Projects:
    - Successfully executed e-prescribing product implementations at 25+ major pharmacy and physician EHR system vendors.
    - Co-led network-wide product improvement initiative to identify system gaps and obstacles; resulted in major product enhancements and creation of net new SOPs.
    - Created standard and state specific Surescripts e-facsimile templates in accordance with state Board of Pharmacy regulations for all 50 states and the District of Columbia.

### Pharmacist / Pharmacist Intern / Pharmacy Technician
CVS Health | Virginia | Dec 2001–Aug 2005

- Provided drug information service to clinicians and counseled patients on proper use of medication.

– Pharmacy staff supervision, inventory management, patient health plan eligibility determination, and medication dispensing.

# Management, Audits, & Compliance Consulting

- **MAK-SYSTEM Group** | Apr 2024–Present
Provide training to MAK-SYSTEM personnel to prepare for FDA audit including content, audit process, and preparedness strategies. Perform a mock audit utilizing the FDA's Quality Systems Guide to Inspections of Quality Systems.  Based on QSR and other applicable 21 CFR Part 800 and ISO 13485 requirements. Will incorporate applicable FDA guidance such as General Principles of Software Validation; Final Guidance for Industry and FDA Staff (2002) and the ISO 14971 and 62304 standards.

- **MedAdvisor Solutions** | Oct 2022–Present
Lead a team of expert Management consultants to provide Strategy, Due Diligence, and SDLC consulting services.

- **Department of Veterans Affairs (VA) Electronic Health Modernization (EHRM) Integration Office (IO) and MITRE Corporation** | Sep 2022 - Jan 2023
Provide SME services focussed on VA Prescribing and Pharmacy workflows and make process and enhancement recommendations

- **Bluesight, Inc.** | Nov 2022–Feb 2023
Lead a team of expert Management consultants to perform management advisory services related to assessment of effectiveness of organizational strategy as executed through technology processes and functions, people, structure, and culture.

- **Electronic Health Record Vendor** | CLIENT CONFIDENTIAL | Feb 2019–Jan 2020
Performing consultation regarding compliance and regulatory matters for Certified Health IT software.

- **Electronic Health Record Vendor** | CLIENT CONFIDENTIAL | Mar 2019–Present
Performing gap analysis and recommendations for improving compliance with CEHRT regulations for Certified Health IT software.

- **REMS–Data, Quality, Process and Systems Review** | CLIENT CONFIDENTIAL | Apr 2019–Present
Performing independent, internal data, quality, process and systems review for a major FDA-regulated REMS (Risk Evaluation and Mitigation Strategies) program and for a popular generic medication with serious side effects. Includes 21 CFR Part 11 compliance review, review of software development, architecture, requirements, documentation, testing and validation; review of annual report data and assisting with responses to FDA inquiries.

- **Electronic Health Record Vendor** | CLIENT CONFIDENTIAL | Nov 2017–Present
Developing guidance to meet CEHRT regulations with a focus on software governance and quality management systems; drafting policies and procedures that combine agile processes with regulatory governance requirements. Reviewing source code and issue tracking records to identify potential regulatory issues.

- **eClinicalWorks, LLC and the Office of the Inspector General of HHS**
**Software Quality Oversight Organization, Team Lead** | July 2017–Feb 2021
Led a team of 15 serving as the Software Quality and Oversight Organization (SQOO) under the Corporate Integrity Agreement between eClinicalWorks LLC and the Office of the Inspector General of the United States Department of Health and Human Services dated May 30, 2017. Served as an independent audit and oversight organization covering a technical review of EHR software and development processes as it relates to patient safety. The project included software process and source code review, including review of past issues, recommendations for risk and quality management systems, design controls, improvements to software development and testing processes, code review and manual and automated code quality analysis.

- **Agency for Healthcare Research and Quality** | Rockville, MD | Mar 2005–Aug 2005
Analyzed current industry Prior Authorization (PA) workflows and standardized clinical PA questions to create an electronic question database for standards creation.

- **National Library of Medicine** | Bethesda, MD | Nov 2004–Jan 2005
Analyzed the RxNorm clinical drug terminology and assessed the scope, feasibility, and integration into existing pharmacy and provider e-prescribing workflows.


# Litigation Consulting

- **Teri Ginnan, Estate of Edward J. Ginnan, IV, Deceased v. <u>Tanmay P. Patwa, M.D., Southwest Infectious Disease Associates</u>, <u>and Silver Cross Hospital and Medical Centers</u>** | Feb 2024–Present
Jurisdiction: Circuit Court of Illinois, Twelfth Judicial Circuit, Will County
Case Number: 20 L 509
Counsel: Langhenry, Gillen, Lundquist & Johnson, LLC
Nature of Suit: Medical Malpractice

- **Austin Roberts v. <u>Iowa Health System, Trinity Medical Center, Afzal Abdullah, M.D., Michael Barr, M.D., Ubaid Sherwani, M.D., Rajesh Alla, M.D., Quad Cities Nephrology Associates, Steven Cremer, M.D. and Iowa Physicians Clinic Medical Foundation</u>** | Nov 2023–Present
Case Number: 2020 L 76
Counsel: Quinn Johnston
Nature of Suit: Medical Malpractice

- **Patricia Natiss v. <u>Kenneth Natiss</u>** | Oct 2023–Present
Jurisdiction: Stamford Superior Court
Case Number: FST-CV21-5024830-S
Counsel: Cohen and Wolf, P.C.
Nature of Suit: Divorce Settlement

- **Lena Williams v. Kaiser** | Sept 2023–Present
Jurisdiction: California
Case Number: 17508
Counsel: Williams Law Firm
Nature of Suit: Breach of Contract, Medical Malpractice, Arbitration

- **<u>Pioneer Rx, LLC</u> v. Danwins, LLC** | June 2023–Present
Jurisdiction: Louisiana Western District
Case Number: 5:21-cv-01738
Counsel: Kirkland & Ellis, LLP
Nature of Suit: Trade Secret

- **<u>Arianne McCain</u> v. Northwestern Memorial Healthcare., et. al.** | Mar 2023–Present
Jurisdiction: Circuit Court, Cook County Illinois
Counsel: Motherway & Napleton, LLP
Nature of Suit: Medical Malpractice
Health IT System: Epic
Review and analyze electronic health records, audit trails, and InBasket messages

- **Joao Martins v. <u>Michael Curi, M.D.</u>, et. al.** | Feb 2023
  Jurisdiction: Superior Court of New Jersey, Law Division: Middlesex County
  Counsel: Farkas & Donohue, LLC
  Nature of Suit: Medical Malpractice
  Health IT System: Sunrise McKesson (Now Allscripts)
  Review and analyze electronic health records, audit trails, to determine edits made to clinical notes.

- **<u>Hayden Mac Ingram</u> v. Cerner Health Services., et. al.** | Feb 2023–Present
  Jurisdiction: Circuit Court Of Jefferson County, Alabama
  Counsel: Hare, Wynn, Newell & Newton, LLP
  Nature of Suit: Medical Malpractice
  Health IT System: Cerner
  Review and analyze electronic health records, system configurations, and system generated artifacts along with internal development documents to determine the nature of microbiology laboratory results display.

- **Sarah Trotta v. <u>Community Health Network,</u> et. al.** | Oct 2022–Jan 2023
  Jurisdiction: Marion County Indiana Superior Court
  Counsel: Zeigler Cohen & Koch
  Nature of Suit: Medical Malpractice
  Health IT System: Epic
  Review and analyze electronic health records and EHR configurations for display of laboratory results.

- **<u>Andrew Puglisi</u> v. Maria N. Musso, D.O., et. al.** | Sept 2022–Oct 2022
  Jurisdiction: Supreme Court of the State of New York, County of Queens
  Counsel: Bamundo Zwal Schermerhorn & Caffrey, LLP
  Nature of Suit: Medical Malpractice
  Health IT System: eClinicalWorks (eCW)
  Review and analyze electronic health records, audit logs, and determine what information has been shared and with whom.

- **Tony L. Sylvester v. University of S. Alabama Health Services Foundation et. al. (representing named defendant, <u>Laboratory Corporation of America Holdings</u>)** | Jul 2022–Present
  Assisting with the review of produced electronic health record information relevant to the case and providing analysis regarding industry standards for integration of electronic laboratory results into electronic health record software.

- **Estate of David Rose and Carol Ann Rose v. <u>Medical Information Technology Inc.</u>** | Apr 2022–June 2022
  Jurisdiction: Superior Court of New Jersey
  Counsel: Sills Cummis & Gross P.C.
  Nature of Suit: Medical Malpractice
  Perform forensic analysis to evaluate and recreate medication prescription generation and transmission of prescriptions to pharmacies. Review and analyze electronic health record audit logs, system configurations, and system generated artifacts.


# Publications

- **Health Affairs** | 2018
  *A Prescription for Enhancing Electronic Prescribing Safety*

- **The American Journal of Managed Care** | 2017
  *A Better Way: Leveraging a Proven and Utilized System for Improving Current Medication Reconciliation* Processes

- **JAMA Internal Medicine** | 2016
  *Analysis of Prescribers' Notes in Electronic Prescriptions in Ambulatory Practice*

- **Journal of the American Medical Informatics Association** | 2015
  *Evaluating the Implementation of RxNorm in Ambulatory Electronic Prescriptions*
- **Journal of Managed Care & Specialty Pharmacy** | 2015
  *Analysis of National Drug Code Identifiers in Ambulatory E-Prescribing*
- **Journal of the American Medical Informatics Association** | 2014
  *Towards creating the perfect electronic prescription*
- **American Journal of Medical Quality** | 2014
  *A Continuous Quality Improvement Initiative for Electronic Prescribing in Ambulatory Care*
- **Applied Clinical Informatics** | 2014
  *Evaluation of a User Guidance Reminder to Improve the Quality of Electronic Prescription Messages*
- **Surescripts** | 2011
  *A Standard Terminology for Classifying Problems on Electronic Prescription Orders in Ambulatory Care*
- **Annals of Pharmacotherapy** | 2007
  *Perioperative Nesiritide Versus Milrinone in High-Risk Coronary Artery Bypass Graft Patients*
- **Agency for Healthcare Research and Quality** | 2007
  *Maximizing the effectiveness of e-prescribing between physicians and community pharmacies*

## Patent Applications

- ***Method and apparatus for quality control of electronic prescriptions***
  United States Patent Application 20120016687
  Inventors: Ajit Dhavle, David Yakimischak

- ***Method and apparatus for quality control of electronic interactions between pharmacies and prescribers***
  United States Patent Application 20130179177
  Inventors: Ajit Dhavle, David Yakimischak

## Selected Industry Projects

- *Report on the Safe Use of Pick Lists in Ambulatory Care Settings: Issues and Recommended Solutions for Improved Usability in Patient Selection and Medication Ordering* | 2016
  Prepared for **Office of the National Coordinator for Health Information Technology**. Prepared by RTI International.

- *E-Prescribing Quality Guidelines* | **Surescripts** | 2016

- *Safe Prescribing: Leveraging the Latest SCRIPT Enhancements* | **ComputerTalk** | 2016

- *Children's EHR Format Enhancement: Final Recommendation Report* | 2015
  Prepared for: **Agency for Healthcare Research and Quality**. Prepared by RTI International.

- *A Prescription for e-Prescribers: Getting the Most Out of Electronic Prescribing* | 2015
  **Office of the National Coordinator for Health Information Technology**

- *Charting a Course to Medication Safety through HIT* | 2014
  **American Pharmacists Association**

- *NCPDP Recommendations and Guidance for Standardizing the Dosing Designation on Prescription Container Labels of Oral Liquid Medications* | 2014

**National Council for Prescription Drug Programs**

- *A Toolset for E-Prescribing Implementation in Independent Pharmacies* | 2011
Prepared for: **Agency for Healthcare Research and Quality**. Prepared by RAND Corporation.

- *A Toolset for E-Prescribing Implementation in Physician Offices* | 2011
Prepared for: **Agency for Healthcare Research and Quality**. Prepared by RAND Corporation.

- *Evaluation of the NCPDP Structured and Codified Sig Format for e-prescriptions* | 2011
Prepared for: **Centers for Medicare and Medicaid Services Office of E-Health Standards and Services**. Prepared by RAND Corporation.

# Education

**Doctor of Pharmacy**
Shenandoah University | 2005

**Master of Business Administration**
Shenandoah University | 2005

# Certifications

**Pharmacist License**
Commonwealth of Virginia | Current

**Lean Six Sigma Black Belt – Blended**
American Society for Quality | 2011

# Professional Associations

- **Member**, Healthcare Information and Management Systems Society (HIMSS)

- **Attendee**, National Council for Prescription Drug Programs (NCPDP)

- **Rho Chi Society**, Gamma Omicron Chapter | Pharmacy's Academic Honor Society

- **Phi Lambda Sigma**, Beta Phi Chapter | National Pharmacy Leadership Society