

## Curriculum Vitae

**Kathleen Jackson, R.Ph., Ph.D. (H.C.), F.A.P.C.**  
CISCI

Jackson Audit and Compliance  
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## Summary of Expertise

40+ years as a licensed pharmacist with 22 years as an owner of a community pharmacy. 13+ years as an accreditation surveyor and consultant, 8+ of those years also performing/reporting on State Board of Pharmacy Inspections/Audits/Assessments for multiple states. Specialized training and experience in both non-sterile and sterile compounding. Presenter and author.

Areas of compounding expertise include:

- USP Chapter <795> non-sterile compounding
- USP Chapter <797> sterile compounding
- USP Chapter <800> hazardous compounding
- FDA Inspections and 483 Responses
- TSBP Management Consultant
- Compounding Processes
- Safety in Compounding
- Sterility Testing
- Endotoxin Testing
- Environmental Monitoring
- Reviewing Certification Reports
- Reviewing Microbiological Data
- Beyond Use Dating
- Documentation of Quality Control and Quality Assurance
- Root Cause Analysis in Quality Issues
- Corrective Action Plans for Quality Related Events
- Self-Assessment of Pharmacy
- Affidavits of Merit/Expert Reports
- Investigational Study Development
- Inspections and Inspection Reports for Boards of Pharmacy
- Monitor for BOP Agreed Board Orders
- Qualified Drug Compliance Expert, Pharmacy Monitoring for FDA
- Review Prescription Pricing Regarding Usual and Customary Fees
- Pharmacological Reviews

## Education

- B.S., 1982 Bachelor of Science in Pharmacy, University of Houston
- A.S., 1979 Associate of Science, San Jacinto Junior College

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## Licenses

- #26396 Expiration 11/30/2024 Texas State Board of Pharmacy

## Employment and Affiliations

### Jackson Audit and Compliance

*Owner & President, June 2014-Present*

- Independent Consultant/Auditor for pharmacy compliance
- Inspector/Monitor for Boards of Pharmacy and Independent Pharmacies
- Qualified FDA Drug Compliance Expert
- Expert Witness for Pharmaceutical Cases, and Prescription Billing Reviews
- Instructor, Sterile Compounding and USP Chapter <800> Requirements

### Optimal Health Hub

*Owner & President, June 2004-Present*

- Alternative and Complimentary Medicine

### Accreditation Commission for Health Care (ACHC)

*Contracted Surveyor, June 2014-Present*

- Perform on-site surveys for compliance with accreditation standards and pertinent USP Chapters
- Prepare survey reports
- Perform on-site inspections for non-resident pharmacy licenses for pharmacies performing sterile compounding on behalf of the Boards of Pharmacy, for the following states: TX, FL, OK, LA, SD, MI
- Collect testing samples while maintaining the chain of custody between the pharmacy, ACHC, and the lab
- Review Continuous Quality Improvement processes and documentation
- Review survey reports, edit and finalize for clients
- Review corrective action plans submitted from clients
- Communicate with clients via telephone to discuss compliance
- Review annual submissions submitted from clients and recommend corrective actions

### Pharmacy Compounding Accreditation Board

*Contracted Surveyor, June 2009 – June 2014 (This organization was absorbed by ACHC in 2014.)*

- Perform on-site surveys for compliance with accreditation standards and USP
- Review survey reports, edit and finalize for clients
- Review corrective action plans submitted from clients
- Communicate with clients via telephone to discuss compliance
- Review annual submissions submitted from clients and recommend corrective actions
- Perform on-site inspections for non-resident pharmacies performing sterile compounding for the following states: TSBP, FL, SD, OK, LA
- Collect samples while maintaining the chain of custody between the pharmacy, ACHC, and the lab
- Review Continuous Quality Improvement processes and documentation
- Prepare reports for and present them to the Accreditation Committee

Relief Pharmacist: Houston, Texas

*April 2010-June 2014*

- Village Compounding Pharmacy, Houston, Texas- *August 2010-June 2014*  
(Supervising Pharmacist and Pharmacist in Charge of Clinical Trials)
- The Medicine Shoppe, La Porte, Texas- *August 2010-August 2012*

ACS-Pharmdur, ACS-Xerox, Philadelphia, PA

*September 2009-December 2012*

*Pharmacy Claims Auditor, achieving a status of Fraud Auditor*

- Perform pharmacy claims audits for Insurance Companies Clients
- Perform pharmacy claims fraud audits

Reese Pharmacy, Inc DBA The Family Pharmacy, La Porte, Texas

[Sold January 2008]

*November 1986-January 2008*

*Founder, Pharmacist in Charge, & President,*

- Coordinate all aspects of operations and all daily processes
- Personnel hiring, management, and payroll
- Management of nine staff members, including pharmacy technicians
- Purchasing, inventory control, and budgeting
- Creating pricing structure
- Equipment maintenance and repair
- Marketing and Advertising
- Kept abreast of industry trends
- Legal Compliance
- Procured third-party contracts
- Education and Training of Staff
- Provide patients with the latest, most up-to-date treatment options available
- Interaction with the community through various civic activities and events
- Promote natural medicine through involvement in advocacy organizations at the state and national levels, by lobbying legislation
- Develop a successful compounding practice
- Built a consultation practice that served as a training center for residents, pharmacy students and UTMB CAM students. Preceptor for University of Houston and University of Texas.
- Achieved three perfect TSBP compliance audits
- Marketing included speaking engagements on many subjects including bio-identical hormone replacement and many health and wellness subjects.
- Built a profitable insurance based independent community pharmacy that achieved \$ 1.2 million annually in sales (1986-1998). Shifted to compounded cash only non-insurance based non-sterile and sterile compounding independent community pharmacy (1998-2008). Achieved 40 compounded prescriptions per day within two years and ultimately reached 75 prescriptions per day with \$ 390 thousand annually in sales

Walgreen Company

*September 1986 - November 1986*

Relief pharmacist

### Walgreen Company

September 1985 - September 1986

Store Manager-3400 Gulf Freeway, Dickenson, Texas

- Responsible for total operations of this retail drug store generating \$ 2.4 million in annual revenue
- Special assignment as inventory specialist to reduce and eliminate excess inventory of \$ 250,000, accomplished 4 months ahead of deadline, which improved the net profit \$ 21,000 in three months.
- Achieved the first internal audit grade of "Excellent" at this location

### Walgreen Company

August 1982 – August 1985

Store Manager- 2221 E. Southmore, Pasadena, Texas

- Responsible for total operations of this retail drug store through the efforts of three assistant managers and twenty-two employees, including three registered pharmacists generating, \$ 2.4 million in annual revenue
- Responsible for advertising and promotion for nineteen stores in the district
- Achieved the first internal audit grade of "Excellent" at this location

December 1981 – August 1982

Assistant Store Manager – 2221 E. Southmore, Pasadena, Texas

- Learned all in-store operations: personnel hiring and management, payroll, corporate record keeping, pharmacy, purchasing, inventory control, in-store promotions/advertising, equipment maintenance and repair

### **Professional Development**

- CISCI renewal 2021 Aug. 30 - renewed June 7, 2023
- 2021-January 5, Immunization Certificate, American Pharmacists Association
- 2022 Nov 17 – USP General Chapter <795> Pharmaceutical Compounding
- 2022 Nov 16 - USP General Chapter <800> Hazardous Drugs
- 2022 Nov 15 – USP General Chapter <797> Pharmaceutical Compounding
- 2019 June 14 - USP General Chapter <795> Pharmaceutical Compounding (December 1, 2019-Appealed/Remanded) – Non-sterile Preparations
- 2019 June 13, 2020 Oct. 23 - USP General Chapter <800> Hazardous Drugs– Handling in Healthcare Settings NABP/USP
- 2019 June 12 - USP General Chapter <797> Pharmaceutical Compounding (December 1, 2019-Appealed/Remanded) – Sterile Preparations NABP/USP
- 2018 November 5 - Certification in Sterile Compounding for Inspectors, (CISCI), NABP/Critical Point, Totowa, NJ (Expiration November 5, 2021-Renewed: Exp. December 30, 2022)
- 2018 June 12 - Sterile Compounding Boot Camp, Totowa, NJ
- 2017 August 25 - Sterile Compounding Instructor Training, Teaching Sterile Compounding and Aseptic Technique Austin Community College
- 2016 – Certificate of Completion, Consulting Hypnotist-Burt Goldman instructor, Hypnovision

- 2015 August 29 - Sterile Compounding Boot Camp, Critical Point, Denver Colorado
- 2013 March 29 - Sterile Compounding Boot Camp, Critical Point, Denver Colorado
- 2013, June 22-24 - The Basic Traditional Chinese Medicine Course (50 hours), East-West Acupuncture Seminars
- 2012 January 23 - Certified Life Coach (certificate no. 3497), American University of NLP
- 2010 April 24-25 - TRINU Healthcare, Sterile Pharmaceutical Compounding, April, Dallas, Texas
- 2004 June – Diploma in Homeopathic Medicine, Westbrook University
- 2004 April 15 - Doctor of Naturopathy Medicine, Westbrook University
- 2004 - Clinical Medicine Residency (12 hours), Pan American University of Natural Medicine, Nevis, WI
- 2004 February 21-22 - Functional Endocrinology (12 hours), University of Bridgeport, Houston, Texas
- 2003 - Jade/Derma Ray/Sound Therapy/ Ozone Therapy/ Inversion Therapy Courses Pan American Institute, Nevis, WI
- 2003 - Level One Residency Pan American University of Natural Medicine, Nevis, WI
- 2002 - Osteoporosis Care Certificate, NIPCO, Disease Management, San Antonio, Texas
- 2002 April 24 - Aseptic Compounding; PCCA, Houston, Texas (8 hour refresher)
- 1998 Jan. 18-20 - Aseptic Compounding; PCCA, Houston, Texas (20 hours)
- 2003 - 2016 NAET Certification, Basic (April 2003, March 2015); Advanced I (October 2003, March 2015); Advanced II A, D, E, F, G, H, I, P T, Z (October 2003 through October 2016), Buena Park, California

### **Advisory Boards**

- 2020-2024 American Pharmaceutical Association Advisory Board for the Sterile Compounding Review and Recertification Program
- 2001-2010 Texas Pharmacy Editorial Advisory Board

### **Preceptorships**

- 2003- 2008 Rotation Site for University of Texas Medical Branch Alternative and Complimentary Medicine, Galveston, Texas
- 2003- 2008 Preceptor, University of Texas College of Pharmacy
- 1997- 2008 Preceptor, University of Houston College of Pharmacy

## **Presentations by Invitation**

- *USP Chapter <795> Changes Part 1: Personal Hygiene and Personnel Training*: January 22, 2024, ACHCU Academy, Orlando, FL.
- *USP Chapter <795> Changes Part 2: Cleaning, Sanitizing, and Environmental Monitoring*: January 22, 2024, ACHCU Academy, Orlando, FL.
- *USP Chapter <795> Changes Part 2: BUDs and Water Activity*: January 22, 2024, ACHCU Academy, Orlando, FL.
- *Building Quality Into the Compounding Process: Perspectives Before and After the Inspection: Perspectives from a Surveyor*: February 8, 2023, USP Third Annual Workshop-Evolution and Advances in Compounding
- *USP Chapter <800>: How To Apply The Chapter*, Instructor for 10 hour ACPE credit for participants, September 22-23, 2020
- *Hidden Emotions in Cancer*, Co-Presenter: Kathleen and Patrick Jackson, January 31, 2016, 2016 International Physician's Round Table & World Congress of Natural Medicines
- *Herbal Vinegars*, SMOCH World Congress, Nevis, West Indies, June 5, 2014
- *Total Quality Management and PCAB*, Student Pharmacist Compounding Competition, Gainesville, FL, April 22, 2014
- *Are Your Medicines Making You Sick?* La Porte Library, Texas, November 2006.
- *Interference Fields Including Scars and Trauma Areas and Treatment with Laser Pointers*, Integrative Approaches to the Diagnosis and Treatment of Pain Conference, Orlando, Florida, April 2005.
- *Boning Up On Osteoporosis*, Houston Yacht Club Women's Sailing Group, La Porte, Texas (2003)
- *Bio-Identical Hormone Replacement Therapy*, University of Texas Medical Branch Journal Club, Galveston, Texas (2003)
- *CoQ10 Deficiency*, University of Texas Medical Branch Journal Club, Galveston, Texas (2003)
- *Expanding the Pharmacy Pain Consult*, PCCA International Seminar, Houston, Texas (2003), Woodbine, Iowa (2003)
- *Intrathecal Compounding, The Role of the Community Compounding Pharmacist*, Elan Pharmaceuticals, San Diego, California (2003)
- *B Vitamin (P5P) Deficiencies*, PCCA International Seminar, Houston, Texas (2002)
- *Pain Management*, PCCA International Seminar, Houston, Texas (2002)
- *Stress Testing and Management*, PCCA International Seminar, Houston, Texas (2001)
- *Billing Intrathecal Solutions*, PCCA International Seminar, Houston, Texas, (2000)

## **Peer Reviewed Publications**

- Jackson, Kathleen. "Drug Utilization: Our Patients Deserve Our Best:", *International Journal of Pharmaceutical Compounding* 27.6 (November/December 2023): 450-453.
- Cabaleiro, Joe and Jackson, Kathleen. "Root Cause Analysis, Part 2: Sterile Compounding" *International Journal of Pharmaceutical Compounding* 20.2 (March/April 2016): 99-104.
- Cabaleiro, Joe and Jackson, Kathleen. "Root Cause Analysis, Part 1: Nonsterile Compounding" *International Journal of Pharmaceutical Compounding* 19.6 (November/December 2015): 465-469.
- Jackson, Kathleen. "The Management of Anemia Part 2: Supplementation and Treatment", *U.S. Pharmacist*, (December 2005);60-70.
- Jackson, Kathleen. "The Management of Anemia Part 1: Nutritional Deficiency Anemias" , *U.S. Pharmacist*, 30.12 (October 2005).
- Jackson, Kathleen. "Autism Is Treatable, Response to Treatment with NAET in an Autistic Patient" *The Journal of NAET*, (Summer 2005).
- Jackson, Kathleen. "The Role of Zinc In Men's Health" *U.S. Pharmacist*, (August 2005;8:29-34).
- Jackson, Kathy. "Navigating the Hormone Highway With BHRT" *Texas Pharmacy*, (Spring 2004).
- Jackson, Kathleen. "Insulin, Too Much is NOT a Good Thing" *Texas Pharmacy*, (Fall 2003:14-15, 30).
- Jackson, Kathy. "Hormone Replacement: Not Just For Women" *Texas Pharmacy*, (Spring 2003): 30-32.
- Jackson, Kathy. "Healthful Living: Good Practices for Good Health" *International Journal Compounding Pharmacists*, 6.3 (May/June 2002):164-166.
- Jackson, Kathy. "Nutrient Depletion Through Prescription Medication" *Texas Pharmacy*, (Spring 2002):10-11, 34.

## **Memberships/Professional Organizations**

- 2021-2024 American Pharmacists Association (Formerly American Pharmaceutical Association), member, Ad Board for Sterile Compounding Certificate Continuing Education (2021-2024)
- 2020-2021 American College of Apothecaries, Faculty, Compounding Training Instructor, member (2020)
- 1997-present Professional Compounding Centers of America (Inactive as of 2008)
- 1998-present Alliance for Pharmacy Compounding Fellowship Committee Chair (2022-2023) (Formerly International Academy of Compounding Pharmacists) Fellow (2001 – present); Board of Directors (2000-2006); Compounders on Capitol Hill Chair (2001, 2002); Membership Chair (2002); Accreditation Committee Chair (2002-2003)
- 2002-2004 Alliance for Pharmacy Compounding - Foundation Board of

Directors, (Formerly International Academy of Compounding Pharmacists Foundation), President (2004), President-Elect (2002-3)

- 2016-present National Guild of Hypnotists
- 2003-present Nambudripad's Allergy Research Foundation
- 2002-2008 Member UTMB Alternative Medicine Journal Club
- 1982-2010 Texas Pharmaceutical Association, Academy of Compounding Section (2002-2004) (Chair-elect 2002, Chair 2003)
- 1982-2004 American Pharmaceutical Association
- 1982-2005 National Community Pharmacist's Association
- 1983-2007 Harris County Pharmacy Association

### **Honors and Awards**

- 2014, June 7 Doctor of Philosophy (Honoris Causa) in Hospitalier and Indigenous Medicine, Pan American University of Natural Medicine, Nevis, WI
- 2002 March Pharmacist of the Month, Professional Compounding Centers of America, Houston, Texas
- 1981-1982 May Roche Pharmacy Communications Award, University of Houston, Houston, Texas

### **Volunteer Community Organizations**

- 1993-2000 La Porte Education Foundation, Vice-President Allocations 1993-98, Advisory Council 1998-2000