1. Kaf al-Ghazal S. The valuable contributions of Al-Razi (Rhazes) in the history of pharmacy during the Middle Ages. *J Interna Soc History of Islamic Med* 2004; 3: 3–9.
2. Hadzovic S. Pharmacy and the great contribution of Arab-Islamic science to its development (Article in Croatian). *Med Arh* 1997; 51(1–2): 47–50.
3. Wikipedia. *Compounding.* [Wikipedia Website.] Available at: en.wikipedia.org/wiki/Compounding. Accessed July 7, 2015.
4. National Conference of State Legislatures. *State Regulation of Compounding Pharmacies.* [NCSL Website.] Updated October 1, 2014. Available at: www.ncsl.org/research/health/regulating-compounding-pharmacies.aspx. Accessed July 8, 2015.
5. Wynkoop K. Compounded Products: Use, Regulation, and Risk. *Digest* Fall 2012 [OMIC Website.] Available at: www.omic.com/compounded-products-use-regulation-and-risk. Accessed July 7, 2015.
6. U.S. Department of Health & Human Services. U.S. Food and Drug Administration. *About FDA: The 1938 Food, Drug, and Cosmetic Act.* [FDA Website.] Updated April 9, 2009. Available at: www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/ucm132818.htm. Accessed July 8, 2015.
7. U.S. Department of Health & Human Services. U.S. Food and Drug Administration. *Drugs.* Compounding: *Compounding Quality Act. Title I of the Drug Quality and Security Act of 2013.* [FDA Website.] Available at: www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/default.htm. Accessed July 7, 2015.
8. U.S. House of Representatives. *H.R. 3204, the Drug Quality and Security Act: Summary: Bipartisan, Bicameral Legislation to Address High-Risk Drug Compounding Practices and Secure the Pharmaceutical Supply Chain.* September 2013 [U.S. House of Representatives Website.] Available at: democrats.energycommerce.house.gov/sites/default/files/documents/HR-3204-Drug-Quality-Security-Act-One-Pager-2013-9-27.pdf. Accessed July 7, 2015.
9. United States Pharmacopeial Convention, Inc. *United States Pharmacopeia 38–National Formulary 33.* General Notices: 2. Official Status and Legal Recognitions. 1–13, [U.S. Pharmacopeial Convention USP–NF Online Website.] Available at: www.uspnf.com/uspnf/pdf/download?usp=38&nf=33&s=0&q=usp38nf33s0_m99989.pdf&officialOn=May 1, 2015&target=oldwindow&time=1438174067008. Accessed July 28, 2015.
10. United States Pharmacopeial Convention, Inc. *United States Pharmacopeia 38–National Formulary 33.* General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations. 559–567. Revised December 1, 2015. [U.S. Pharmacopeial Convention USP–NF Online Website.] Available at: www.uspnf.com/uspnf/pdf/download?usp=38&nf=33&s=2&q=usp38nf33s2_c795.pdf&officialOn=December 1, 2015&target=oldwindow&time=1435157142228. Accessed July 1, 2015.
11. United States Pharmacopeial Convention, Inc. *United States Pharmacopeia 38–National Formulary 33.* General Chapter <797> Pharmaceutical Compounding – Sterile Preparations. 567–610. Revised December 1, 2015. [U.S. Pharmacopeial Convention *USP–NF* Online Website.] Available at: www.uspnf.com/uspnf/pdf/download?usp=38&nf=33&s=2&q=usp38nf33s2_c797.pdf&officialOn=December 1, 2015&target=oldwindow&time=1435157555222. Accessed July 1, 2015.
12. United States Pharmacopeial Convention, Inc. *United States Pharmacopeia 38–National Formulary 33.* General Chapter: <1160> Pharmaceutical Calculations in Prescription Compounding. 1303–1317. Revised December 1, 2015. [U.S. Pharmacopeial Convention *USP–NF* Online Website.] Available at: www.uspnf.com/uspnf/pdf/download?usp=38&nf=33&s=2&q=usp38nf33s2_c1160.pdf&officialOn=December 1, 2015&target=oldwindow&time=1435157927447. Accessed July 1, 2015.
13. United States Pharmacopeial Convention, Inc. *United States Pharmacopeia 38–National Formulary 33.* General Chapter: <1163> Quality Assurance in Pharmaceutical Compounding. 1317–1324. Revised December 1, 2015. [U.S. Pharmacopeial Convention *USP–NF* Online Website.] Available at: www.uspnf.com/uspnf/pdf/download?usp=38&nf=33&s=2&q=usp38nf33s2_c1163.df&officialOn=December 1, 2015&target=oldwindow&time=1435095650721. Accessed July 1, 2015.
14. United States Pharmacopeial Convention, Inc. *United States Pharmacopeia 38–National Formulary 33.* General Chapters: <1176> Prescription Balances and Volumetric Apparatus. 1331–1332. Revised December 11, 2015. [U.S. Pharmacopeial Convention *USP–NF* Online Website.] Available at: www.uspnf.com/uspnf/pdf/download?usp=38&nf=33&s=2&q=usp38nf33s2_c1176.pdf&officialOn=December 1, 2015&target=oldwindow&time=1435158376509. Accessed July 8, 2015.
15. United States Pharmacopeial Convention, Inc. *United States Pharmacopeia 38–National Formulary 33.* General Chapters: <1191> Stability Considerations in Dispensing Practice. 1381–1385. Revised December 1, 2015. [U.S. Pharmacopeial Convention *USP–NF* Online Website.] Available at: www.uspnf.com/uspnf/pdf/download?usp=38&nf=33&s=2&q=usp38nf33s2_c1191.pdf&officialOn=December 1, 2015&target=oldwindow&time=1435095740121. Accessed July 7, 2015.
16. United States Pharmacopeial Convention, Inc. *United States Pharmacopeia 38–National Formulary 33.* General Chapters on Compounding. [U.S. Pharmacopeial Convention *USP–NF* Online Website.] Available at: www.usp.org/usp-healthcare-professionals/compounding/compounding-general-chapters. Accessed July 7, 2015.
17. Department of Health and Human Services. U.S. Food and Drug Administration. *Code of Federal Regulations. Title 21 – Food and Drugs, Chapter 1. Subchapter C –Drugs: General, Part 210 Current Good Manufacturing Practice in Manufacturing, Processing Packing, or Holding of Drugs: General.* (Revised as of Revised April 1, 2014) [U.S. Government Publishing Office Website.]Available at: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=210&showFR=1. Accessed July 8, 2015.
18. Department of Health and Human Services. U.S. Food and Drug Administration. *Code of Federal Regulations. Title 21 – Food and Drugs, Chapter 1. Subchapter C –Drugs: General, Part 211 Current Good Manufacturing Practice for Finished Pharmaceuticals.* (Revised April 1, 2014) [U.S. Government Publishing Office Website.] Available at: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=211&showFR=1. Accessed July 8, 2015.
19. Department of Health and Human Services. U.S. Food and Drug Administration. *Code of Federal Regulations. Title 21 – Food and Drugs, Chapter 1. Subchapter D – Drugs for Human Use Part 314 Applications for FDA Approval to Market a New Drug.* (Revised April 1, 2014) [U.S. Government Publishing Office Website.] Available at: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=314&showFR=1. Accessed July 8, 2015.
20. Department of Health and Human Services. U.S. Food and Drug Administration. *Code of Federal Regulations. Title 21 – Food and Drugs, Chapter 1. Subchapter F – Biologics, Parts 600-680 Biological Products.* [U.S. Government Publishing Office Website.] Available at: www.gpo.gov/fdsys/pkg/CFR-2010-title21-vol7/pdf/CFR-2010-title21-vol7-chapI-subchapF.pdf. Accessed July 8, 2015.
21. Department of Health and Human Services. U.S. Food and Drug Administration. *Code of Federal Regulations. Title 21 – Food and Drugs, Chapter 1. Subchapter E – Animals Drugs, Feeds, and Related Products, Parts 500-59.* [U.S. Government Publishing Office Website.] Available at: www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol6/pdf/CFR-2011-title21-vol6-chapI-subchapE.pdf. Accessed July 8, 2015.
22. U.S. Department of Health and Human Services. U.S. Food and Drug Administration. Office of Regulatory Affairs. Center for Drug Evaluation and Research. *Guidance for FDA Stall and Industry. Compliance Policy Guides Manual. Sec 460.200. Pharmacy Compounding*. May 2002 (Withdrawn). [FDA Website.] Available at: www.fda.gov/ohrms/dockets/98fr/02d-0242_gdl0001.pdf. Accessed July 29, 2015.
23. Cornell University Law School. *Thompson v. Western States Medical Center (01-344) 535 U.S. 357 (2002) 238 F.3d 1090, affirmed.* [Cornell University Law School Website.] Available at: www.law.cornell.edu/supct/html/01-344.ZS.html. Accessed November 12, 2013.
24. Leagle. *Wedgewood Village Pharmacy, Inc. v. United States of America. 421 F.3d 263 (3rd Cir. 2005).* [Leagle Website.] Available at: www.leagle.com/decision/2005684421F3d263_1655. Accessed December 4, 2013.
25. Leagle. *Medical Center Pharmacy v. Mukasey. 536 F.3d 383 (5th Cir. 2008).* [Leagle Website.] Available at: www.leagle.com/decision/In%20FCO%2020080718063. Accessed December 4, 2013.
26. Department of Health and Human Services. Food and Drug Administration. Center for Drug Evaluation. *Draft Guidance for Industry: For Entities Considering Whether to Register As Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act. U.S.* [FDA Website.] Available at: www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm434171.pdf. Accessed July 8, 2015.
27. Department of Health and Human Services. U.S. Food and Drug Administration. *Code of Federal Regulations. Title 21 – Food and Drugs, Chapter 1. Subchapter E – Animals Drugs, Feeds, and Related Products, Part 530.13 Extralabel use from Compounding of Approved New Animal and Approved Human Drugs.* [U.S. Government Publishing Office Website.] Available at: www.gpo.gov/fdsys/pkg/CFR-2012-title21-vol6/pdf/CFR-2012-title21-vol6-sec53013.pdf. Accessed July 8, 2015.
28. Department of Health and Human Services. U.S. Food and Drug Administration. *Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA). Animal & Veterinary,*

Guidance, Compliance & Enforcement, Acts, Rules & Regulations. [FDA Website.] Available at: www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/Acts-RulesRegulations/ucm085377.htm. Accessed July 8, 2015.
29. Department of Health and Human Services. U.S. Food and Drug Administration. Center for Veterinary Medicine. *Draft Guidance for Industry Compounding Animal Drugs from Bulk Drug.* May 2015. [FDA Website.] Available at: www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM446862.pdf. Accessed July 8, 2015.
30. Wikipedia. *Quality by Design*. [Wikipedia Website.] Available at: en.wikipedia.org/wiki/Quality_by_Design. Accessed July 28, 2015.
31. Department of Health and Human Services. U.S. Food and Drug Administration. *Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach. A Science and Risk Based Approach to Product Quality Regulation Incorporating an Integrated Quality Systems Approach.* [FDA Website.] Available at: www.fda.gov/ohrms/dockets/ac/03/briefing/3933B1_02_Pharmaceutical%20cGMPs.pdf. Accessed July 28, 2015.
32. Department of Health and Human Services. U.S. Food and Drug Administration. *FDA Strategic Priorities 2014-2018*. September 2014. [FDA Website.] Available at: www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM416602.pdf, Assessed July 28, 2015
33. Department of Health and Human Services. U.S. Food and Drug Administration. Center for Drug Evaluation and Research. Center for Veterinary Medicine. Office of Regulatory Affairs. *Guidance for Industry PAT — A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance. Pharmaceutical CGMPs*. September 2004. [FDA Website.] Available at: www.fda.gov/downloads/Drugs/Guidances/ucm070305.pdf. Assessed July 28, 2015.
34. R. J. Hedges & Associates. *Pharmacy Compounding Policy and Procedure Program.* [R.J. & Associates Website.] Available at: www.rjhedges.com/services/compounding-program. Accessed June 30, 2015.

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