



## Lippert, Inc.

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### **GMP Consulting Services**

Lippert, Inc. specializes in helping small, starts up pharmaceutical firms establish efficient, cost effective quality systems that will pass inspection and produce high quality products. We work with firms to review current systems to make them more efficient and robust enough to stand up to current regulatory challenges.

For our Fitzsimmons clients we offer 2-hour FREE consultation to determine your needs and how we can best assist you and \$30 discount off our normal hourly rate of \$175 per hour. Fitzsimmons rate billed at \$145 per hour.

[Auditing](#): Perform supplier qualification as well as internal auditing for GMP providing a very detailed, specific report of findings and recommended actions, including full references to the pertinent regulations and guidance documents.

[Quality Systems](#): Can create, review, implement or improve GMP Quality Systems including CAPA management/trending, GxP training programs, Risk Assessment programs, equipment preventative maintenance, and much more.

[Computer Validation](#): We can write the SOPs, Master Plans, and protocols required to make sure your systems are fully validated and compliant with 21 CFR Part 11 Electronic Records, Electronic Signatures.

[Management](#): We can assist with management strategies, especially for small companies that want to set up the most cost effective and efficient compliance team possible with limited resources.

[Training](#): We can bring GxP training programs to your site and/or assist you with setting up ongoing training programs needed for compliance..