

Audit Readiness Assessments



Will your site will pass a PIC/S, FDA, or TGA audit?

PharmOut offers onsite audit-readiness assessments to determine if your site is ready for an audit by a regulatory body.

Following the GMP principles laid out in PICS and FDA CFR 210/211, we use a risk-based approach to prioritise the areas to be assessed for GMP compliance.

With our extensive experience in the manufacture of pharmaceutical:

- excipients
- active pharmaceutical ingredients
- final dosage forms and
- steriles,

we know which areas an auditor will target in each type of manufacturing plant. We can also assess clinical trial facilities.

An audit-readiness assessment will typically take 2-3 days on your site. Depending on the plant size this would involve 1-2 consultants.

Upon arrival, they will determine which regulations you have to comply with and will start with the most rigorous. If you have to comply with multiple regulations, they will check your compliance against the nuances of each.

Our consultants' primary target will be the sufficiency and robustness of your Quality Management System. They'll then check the compliance to that system.

At the end of the audit-readiness assessment, you will receive a detailed report. The report will list all the non-compliances our consultants discovered. It will also include a prioritised action plan of the areas you should address.

To book an audit-readiness assessment please contact PharmOut. Contact information can be found on: www.pharmout.net