

Before Adding a Named QP

Adding a named QP to your manufacturing authorisation isn't simply an administrative step. Before taking on the role, a QP needs enough understanding of your site, products and Pharmaceutical Quality System to support the site effectively from day one.

BEFORE ADDING A NAMED QP, ASK: _____

- ☐ Is the scope of responsibility clearly defined?
- ☐ Does the QP have relevant experience for our products and manufacturing environment?
- ☐ Have they had enough time to understand our Pharmaceutical Quality System?
- ☐ Will they have appropriate access to people, systems and information?
- ☐ Is the expected certification and wider quality workload realistic?
- ☐ Are escalation routes and decision-making responsibilities clear?
- ☐ Does the arrangement complement the responsibilities of our internal Quality and Manufacturing teams?
- ☐ Will the support model still work if manufacturing activity increases?

Getting these points clear at the outset makes it easier to establish a QP arrangement that works in practice, not just on the manufacturing authorisation.

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for further detail***



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