

# READINESS QUIZ



DATE

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COMPANY

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For the complete ORAT checklist contact us at [admin@engcor.com.au](mailto:admin@engcor.com.au)

## PEOPLE

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Are your people ready?

Category	Items to Verify	Status
<b>Org Chart</b>	Developed and up to date	<input type="checkbox"/>
<b>Position Descriptions</b>	Staff are trained in position and document up to date	<input type="checkbox"/>
<b>Training</b>	All staff trained as per their position	<input type="checkbox"/>
<b>RACI</b>	Clear role and responsibility or RACI matrix for all teams and services	<input type="checkbox"/>
<b>Supplier Qualification</b>	Suppliers onboard and qualified	<input type="checkbox"/>

## PROCESS

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Is your process ready?

Category	Items to Verify	Status
<b>Batch Records</b>	All batch records complete and approved	<input type="checkbox"/>
<b>Validation</b>	Processes, cleaning and method validation executed and approved	<input type="checkbox"/>
<b>Equipment Records</b>	IQ/OQ/PQ protocols complete and reports approved	<input type="checkbox"/>
<b>SOPs</b>	Current, approved versions available	<input type="checkbox"/>
<b>Training Records</b>	All personnel are trained on relevant SOPs	<input type="checkbox"/>
<b>QC / Stability Data</b>	Data matches application submitted	<input type="checkbox"/>
<b>Annual Product Review</b>	Current for all products / devices, trends evaluated	<input type="checkbox"/>

## PREMISES

Is your site ready?

Category	Items to Verify	Status
<b>Manufacturing Areas</b>	Clean, organize and properly labelled and qualified	<input type="checkbox"/>
<b>Line Clearance</b>	Policies developed for line clearance and batch release	<input type="checkbox"/>
<b>Contamination Control</b>	Contamination control strategy and risk assessment established and all staff trained	<input type="checkbox"/>
<b>Equipment</b>	Calibration / maintenance current, qualification complete, properly labelled / tagged	<input type="checkbox"/>
<b>Utilities</b>	Qualified, monitored and maintained	<input type="checkbox"/>
<b>Environmental Controls</b>	Classifications verified and monitored	<input type="checkbox"/>
<b>Storage Areas</b>	Temperature mapping completed and monitored	<input type="checkbox"/>
<b>Warehouse</b>	Inventory accurate, labelling compliant	<input type="checkbox"/>

## SYSTEMS

Are your systems ready?

Category	Items to Verify	Status
<b>QMS</b>	QMS is up to date. Are all deviations, CAPAs and change controls are in an appropriate state	<input type="checkbox"/>
<b>Documents</b>	Documents are up to date and periodically reviewed	<input type="checkbox"/>
<b>Computerized Systems</b>	21 CFR Part 11 compliant, audit trails enabled	<input type="checkbox"/>
<b>Utility Systems</b>	Qualified, monitored and maintained	<input type="checkbox"/>
<b>Safety Systems</b>	Risk assessments established and PPE in place	<input type="checkbox"/>
<b>Crisis Management / Business Continuity</b>	Plans established and routine checks complete	<input type="checkbox"/>

## SUPPORT

Are your support functions established?

Category	Items to Verify	Status
<b>Facility Management</b>	Function established to manage hard and soft services	<input type="checkbox"/>
<b>Waste Management</b>	Waste streams are appropriately segregated and managed. Reporting in place for chemical and clinical waste, where required	<input type="checkbox"/>
<b>Security</b>	Function established, routine access control managed, site induction and contractor management in place	<input type="checkbox"/>
<b>Revalidation</b>	Function established, revalidation assessment complete	<input type="checkbox"/>
<b>QC</b>	Function establish, method validation in place and OOS / trending procedures functioning	<input type="checkbox"/>