


	<b>GILES CHEMICAL ~ PREMIER MAGNESIA</b>		
	<b>Company Form</b>		
	Title: <b>Internal Audit Checklist – Organization and Personnel</b>	Number: <b>Q12-PR-100-F008d</b>	
	Owner: <b>Deborah Durbin</b>	Revision: <b>0</b>	
	Effective Date: <b>12/19/12</b>	Page: <b>1 of 2</b>	

Audit #: \_\_\_\_\_ Auditor(s): \_\_\_\_\_ Date: \_\_\_\_\_

<b>Subpart B</b>		
<b>Responsibilities of the Quality Control Unit – 21 CFR 211.22</b>	<b>Document(s) Reviewed/Person(s) Interviewed/Objective Evidence/Comments:</b>	<b>Conforms to Requirements</b>
Is the quality unit defined – including QA and QC activities – that is independent of production?		<input type="checkbox"/> Yes <input type="checkbox"/> No
Do Quality personnel have established roles and responsibilities covering requirements defined in 21 CFR 211, and have procedures been established to carry out these responsibilities?		<input type="checkbox"/> Yes <input type="checkbox"/> No
Has the Quality Unit operations and authority been established for manufacturing records?		<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the Quality Unit determine if all specifications have been met (in-process, product) and approve/release or reject has been performed on each finished batch for distribution.		<input type="checkbox"/> Yes <input type="checkbox"/> No
Quality control has not approved and released product in any form that does not meet specifications unless a deviation has been investigated and approved by the Quality Unit.		<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the Quality Unit perform cGMP Internal Audits periodically? Is a documented corrective action file is maintained?		<input type="checkbox"/> Yes <input type="checkbox"/> No
Do procedures exist for notifying responsible management in a timely manner of regulatory inspections, serious GMP deficiencies, product defects and related actions (ICH Q7A)?		<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Personnel Qualification and Responsibilities – 21 CFR 211.25 and 211.28</b>	<b>Document(s) Reviewed/Person(s) Interviewed/Objective Evidence/Comments:</b>	<b>Conforms to Requirements</b>
Have procedures been established that define work requirements for personnel to prevent microbial contamination from illness or hygienic practices?		<input type="checkbox"/> Yes <input type="checkbox"/> No

### Controlled Document

Only those quality documents viewed through the Giles Chemical electronic Documentation System are officially controlled. All other copies, whether viewed through another computer program or a printed version, are not controlled and, therefore, the Quality Unit at Giles assumes no responsibility for accuracy of the document.

	<b>GILES CHEMICAL ~ PREMIER MAGNESIA</b>		
	<b>Company Form</b>		
	Title: <b>Internal Audit Checklist – Organization and Personnel</b>	Number: <b>Q12-PR-100-F008d</b>	
	Owner: <b>Deborah Durbin</b>	Revision: <b>0</b>	
	Effective Date: <b>12/19/12</b>	Page: <b>2 of 2</b>	

Have hygienic practices have been established to include appropriate garments, personal hygiene, hand washing and sanitation, etc. prior to starting work and at any time whereby personnel can become soiled/contaminated?		<input type="checkbox"/> Yes <input type="checkbox"/> No
Have procedures been established for removal of jewelry and other items and/or use of appropriate coverings?		<input type="checkbox"/> Yes <input type="checkbox"/> No
Have procedures been established for the use of impermeable gloves, hairnets, beard covers, etc. and for restrictions of food, drinks, gum, tobacco, etc. in areas where product contamination could occur? Have procedures been established to prevent contamination from all extraneous sources?		<input type="checkbox"/> Yes <input type="checkbox"/> No
Are there appropriate change rooms available, if needed, and is there adequate storage of personal effects?		<input type="checkbox"/> Yes <input type="checkbox"/> No
Are personnel qualified and have adequate training, experience and/or education necessary to perform job functions?		<input type="checkbox"/> Yes <input type="checkbox"/> No
Have procedures been established to define requirements for personnel who will supervise activities?		<input type="checkbox"/> Yes <input type="checkbox"/> No
Are personnel who are designated as supervisors qualified and have written requirements?		<input type="checkbox"/> Yes <input type="checkbox"/> No
Have procedures been established and records maintained documenting compliance to these procedures?		<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Consultants – 21 CFR 211.34</b>	<b>Document(s) Reviewed/Person(s) Interviewed/Objective Evidence/Comments:</b>	<b>Conforms to Requirements</b>
Are records of consultants' qualifications and the type of service they provide maintained?		<input type="checkbox"/> Yes <input type="checkbox"/> No

**Controlled Document**

Only those quality documents viewed through the Giles Chemical electronic Documentation System are officially controlled. All other copies, whether viewed through another computer program or a printed version, are not controlled and, therefore, the Quality Unit at Giles assumes no responsibility for accuracy of the document.