

Appendix C

Details on critical suppliers, outsourced processes and OEM not covered by the same quality management system



Product Service




Manufacturer:



Application identification:

Details on critical suppliers, outsourced processes and OEM not covered by the same quality management system (will not appear on the certificate)*:

Please provide for each listed company the respective certificate, e.g. EN ISO 13485, EC Directive, ISO 17025 etc.

				Outsourced processes						
				Design / Development	Production	Product Testing	OEM Manufacturers	Sterilization		
Company name:	<input type="text"/>	Concerns the following products:	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Address:	<input type="text"/>		<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Company name:	<input type="text"/>	Concerns the following products:	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Address:	<input type="text"/>		<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Company name:	<input type="text"/>	Concerns the following products:	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Address:	<input type="text"/>		<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Company name:	<input type="text"/>	Concerns the following products:	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Address:	<input type="text"/>		<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Company name:	<input type="text"/>	Concerns the following products:	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Address:	<input type="text"/>		<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

* E.g. for sterilization, packaging etc.

For the term 'critical supplier' see NBOG BPG 2010-1 and GHTF SG3/N17/2008. www.nbog.eu/2.html

<http://www.imdrf.org/docs/ghrf/final/sg3/technical-docs/ghrf-sg3-n17-guidance-on-quality-management-system-081211.pdf>

For definition of OEM see EK-MED 3.9 B 16. www.zlg.de/medizinprodukte/dokumente/antworten-und-beschluesse-ek-med.html