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ISO 22716 AUDIT PREPARATION CHECKLIST

Demonstrate your commitment to Good Manufacturing Practices for Cosmetic Products

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Achieving ISO 22716 certification demonstrates your commitment to Good Manufacturing Practices (GMP) for cosmetic products, supports compliance and improves operational consistency, reduces errors, and strengthens your reputation in the cosmetics industry.

Thorough preparation for your audit ensures processes are compliant, efficient, and continuously improving. This checklist provides a practical guide to help you identify and address common pitfalls before the audit. By following these steps, you can minimise risks, enhance product quality and safety, and build trust with customers and regulatory bodies.

✓	ACTION	NOTES
1. Quality Management System (QMS)		
☐	Do you have a documented Quality Policy that supports Good Manufacturing Practices (GMP)?	
☐	Are your quality procedures and work instructions clearly documented and accessible?	
☐	Are roles, responsibilities, and authorities clearly defined within your QMS?	
☐	Do you have a system for handling deviations, nonconformities, and corrective actions?	
2. Personnel Training and Hygiene		
☐	Have all employees received training on GMP requirements relevant to their roles?	
☐	Do you maintain up-to-date training records for all staff?	
☐	Are there clear hygiene rules for personnel, including clothing, personal hygiene, and behaviour?	
☐	Are there procedures in place to ensure staff health and hygiene do not compromise product quality?	
3. Premises and Equipment		
☐	Are production areas designed and maintained to minimise contamination risks?	
☐	Is there clear segregation of different manufacturing processes to avoid cross-contamination?	
☐	Is your equipment clean, maintained, and calibrated as required?	
☐	Do you have cleaning and maintenance records for all equipment and facilities?	
4. Raw Materials and Packaging		
☐	Do you have approved suppliers for raw materials and packaging components?	
☐	Is there a system for inspecting and testing incoming raw materials and packaging?	
☐	Are raw materials properly identified, stored, and protected from contamination?	
☐	Do you keep accurate records of supplier certifications and material specifications?	
5. Production and In-Process Controls		
☐	Do you have clear, documented procedures for each stage of the production process?	
☐	Are in-process checks carried out at defined intervals to ensure product quality?	
☐	Do you have controls in place to prevent mix-ups and contamination during production?	
☐	Are batch records complete, accurate, and reviewed regularly?	

6. Finished Product Testing and Release		
☐	Do you have procedures for testing finished products to ensure they meet specifications?	
☐	Is there a defined process for releasing products only after quality approval?	
☐	Are test records and Certificates of Analysis (CoAs) maintained for each batch?	
☐	Do you have procedures for handling nonconforming finished products?	
7. Storage and Distribution		
☐	Are finished products stored in conditions that maintain their quality (e.g., temperature, humidity controls)?	
☐	Is there a system to control inventory and prevent mix-ups or contamination?	
☐	Do you have procedures for the distribution and transportation of products to ensure they remain safe and effective?	
☐	Is traceability maintained throughout the distribution process?	
8. Complaints and Recalls		
☐	Do you have a documented procedure for handling customer complaints?	
☐	Are complaints analysed for trends and used to improve processes?	
☐	Do you have an effective recall procedure to remove defective products from the market?	
☐	DHave you conducted mock recalls to test your recall procedure?	
9. Documentation and Record-Keeping		
☐	Are all records accurate, complete, and retained for the required period?	
☐	Do your records cover all GMP-related activities, including production, quality control, and distribution?	
☐	Are changes to documents controlled and approved appropriately?	
☐	Is document access limited to authorised personnel?	
10. Internal Audits and Management Review		
☐	Do you conduct regular internal audits of your GMP system?	
☐	Are audit findings documented and corrective actions implemented promptly?	
☐	Does senior management regularly review GMP performance and address any issues?	
☐	Are follow-up actions from management reviews documented and implemented?	
Final Check		
☐	Have you addressed all the items in this checklist before your audit?	
☐	Do you feel confident in demonstrating your GMP compliance during the audit?	

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FOR MORE INFORMATION

+44 116 296 1620

ukenquiries@intertek.com

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