

**QC AND LAB OPERATIONS – WR**

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COMPANY NAME: \_\_\_\_\_ DATE: \_\_\_\_\_

FACILITY NAME: \_\_\_\_\_ PHONE NO.: \_\_\_\_\_

WEB SITE: \_\_\_\_\_ FAX NO.: \_\_\_\_\_

ADDRESS: \_\_\_\_\_

CONTACT PERSON: \_\_\_\_\_ EMAIL ADDRESS: \_\_\_\_\_

TITLE: \_\_\_\_\_ PHONE NO.: \_\_\_\_\_

SERVICES TO BE PROVIDED OR AVAILABLE:      MANUFACTURING \_\_\_      ENCAPSULATION \_\_\_

**GENERAL INFORMATION**

1. IS THE COMPANY A DIVISION OR SUBSIDIARY OF ANOTHER CORPORATION? \_\_\_\_\_  
A. IF YES, SPECIFY: \_\_\_\_\_
2. NUMBER OF YEARS IN BUSINESS: \_\_\_\_\_ YEAR FOUNDED: \_\_\_\_\_
3. TOTAL NUMBER OF EMPLOYEES: \_\_\_\_\_ NUMBER OF SHIFTS: \_\_\_\_\_
4. DOES THE FACILITY HOLD ANY THIRD-PARTY CERTIFICATIONS? \_\_\_\_\_
5. HAS THE FACILITY BEEN AUDITED BY THE FDA? IF SO, WHEN? \_\_\_\_\_

**PERSONNEL**

6. TRAINING PROCEDURES
  - A. IS THERE A WRITTEN TRAINING PROGRAM? \_\_\_\_\_
  - B. ARE CURRENT TRAINING RECORDS AVAILABLE? \_\_\_\_\_
  - C. WHAT IS THE FREQUENCY OF THE TRAINING? \_\_\_\_\_
  - D. HOW OFTEN IS cGMP TRAINING PERFORMED? \_\_\_\_\_
7. ARE WRITTEN JOB DESCRIPTIONS AVAILABLE? \_\_\_\_\_
8. DOES EACH PERSON ENGAGED IN TESTING HAVE THE EDUCATION, TRAINING AND EXPERIENCE, OR ANY COMBINATION THEREOF, TO ENABLE THAT PERSON TO PERFORM THE ASSIGNED TASKS? \_\_\_\_\_
9. HOW MANY QUALIFIED / AUTHORIZED PERSONNEL ARE EMPLOYED TO PERFORM AND SUPERVISE THE MANUFACTURE/ENCAPSULATION OF EACH MATERIAL/PRODUCT? \_\_\_\_\_

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**BUILDING / FACILITIES**

10. DESCRIBE THE VENTILATION AND AIR FILTRATION SYSTEMS: \_\_\_\_\_  
\_\_\_\_\_
11. DESCRIBE THE BUILDING/LAB MAINTENANCE PROGRAM \_\_\_\_\_  
\_\_\_\_\_
- A. PLEASE PROVIDE COPIES OF SOPS FOR GENERAL HOUSEKEEPING.
12. WHAT IS YOUR PROCEDURE FOR DESIGNATING AREAS FOR CLEAN AND DIRTY EQUIPMENT AND WORK-IN-PROGRESS? \_\_\_\_\_  
\_\_\_\_\_
13. DESCRIBE THE PEST CONTROL PROGRAM: \_\_\_\_\_  
\_\_\_\_\_
- A. DO QA AND FACILITIES/OPERATIONS APPROVE PESTICIDES? \_\_\_\_\_

**EQUIPMENT**

14. ARE ALL INSTRUMENTS, GAUGES AND RECORDING DEVICES IDENTIFIED WITH UNIQUE EQUIPMENT NUMBERS AND CALIBRATION STATUS? \_\_\_\_\_
15. IS ALL EQUIPMENT CALIBRATION CURRENT? \_\_\_\_\_
- A. ARE THERE APPROPRIATE CALIBRATION RECORDS FOR EACH PIECE OF EQUIPMENT/INSTRUMENTATION?  
\_\_\_\_\_
16. ARE ALL INSTRUMENTS, GAUGES AND RECORDING DEVICES CALIBRATED AT SUITABLE INTERVALS IN ACCORDANCE WITH AN ESTABLISHED WRITTEN PROGRAM CONTAINING SPECIFIC PROCEDURES, SCHEDULES, LIMITS FOR ACCURACY AND PRECISION, AND PROVISIONS FOR REMEDIAL ACTION IN THE EVENT ACCURACY AND/OR PRECISION LIMITS ARE NOT MET? \_\_\_\_\_
17. ARE CALIBRATION STANDARDS APPROPRIATE FOR THE ACCURACY DESIRED, E.G., CLASS 1 WEIGHTS? \_\_\_\_\_
18. ARE "TIME OF USE" CALIBRATIONS PERFORMED AS APPROPRIATE, E.G., DAILY CHECK WEIGHTS ON BALANCES / SCALES? \_\_\_\_\_
19. ARE THE APPROPRIATE WEIGHTS OR OTHER STANDARDS READILY AVAILABLE, E.G., CLASS 1 WEIGHTS? \_\_\_\_\_  
\_\_\_\_\_
20. ARE STANDARDS NIST TRACEABLE? \_\_\_\_\_

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<b>EQUIPMENT (Continued)</b>	
21.	ARE EQUIPMENT AND UTENSILS CLEANED, MAINTAINED AND SANITIZED AT APPROPRIATE INTERVALS TO PREVENT MALFUNCTIONS OR CONTAMINATION THAT WOULD AFFECT TEST RESULTS? _____
22.	ARE THERE WRITTEN PROCEDURES FOR CLEANING AND MAINTAINING EQUIPMENT? _____ A. DO THESE PROCEDURES INCLUDE APPROPRIATE SCHEDULES, DETAILS OF THE METHODS AND MATERIALS USED IN CLEANING AND MAINTENANCE OPERATIONS AND PROCEDURES FOR DOCUMENTING THE CLEANING AND MAINTENANCE? _____ B. ARE THESE METHODS VALIDATED? _____
23.	IS THERE AN EQUIPMENT MAINTENANCE PROGRAM? _____ _____
24.	ARE EQUIPMENT HISTORY FILES MAINTAINED? _____ A. ARE EQUIPMENT MANUALS AVAILABLE? _____
25.	IF EQUIPMENT LOG BOOKS ARE USED, HOW ARE ENTRIES LOGGED? _____ _____ A. ARE ENTRIES IN CHRONOLOGICAL ORDER? _____
26.	IS EQUIPMENT QUALIFIED AS APPROPRIATE (IQ/OQ/PQ)? _____ A. IF NOT PERFORMED, IS JUSTIFICATION DOCUMENTED? _____
27.	DO PROCEDURES SPECIFY THE ROUTINE RE-QUALIFICATION FREQUENCY FOR EQUIPMENT? _____
28.	IF CONTRACTORS ARE USED FOR CALIBRATION, MAINTENANCE OR QUALIFICATION, HAVE THE CONTRACTORS BEEN AUDITED TO ASSURE COMPETENCE? _____
29.	ARE APPROPRIATE CONTROLS IN PLACE TO PREVENT THE OVERWRITING OF ELECTRONIC DATA? _____
30.	ARE REFRIGERATORS, FREEZERS, AND INCUBATORS TEMPERATURE-CONTROLLED AND MONITORED? _____

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**RAW MATERIAL RECEIPT & HANDLING**

31. ARE THERE WRITTEN PROCEDURES DESCRIBING IN SUFFICIENT DETAIL THE RECEIPT, IDENTIFICATION, STORAGE, HANDLING AND DISPOSITION OF RAW MATERIALS? \_\_\_\_\_  
\_\_\_\_\_
- A. DEFINE YOUR PROTOCOL FOR SAMPLING INCOMING RAW MATERIALS UPON RECEIPT. \_\_\_\_\_  
\_\_\_\_\_
- B. ARE THERE ESTABLISHED IDENTIFICATION TESTS FOR ALL RAW MATERIALS & FINISHED PRODUCTS? \_\_\_\_\_  
\_\_\_\_\_
- C. ARE THERE SPECIFIC PROCEDURES FOR THE RECEIPT, HANDLING, IDENTIFICATION, AND STORAGE OF DANGEROUS, TOXIC, AND/OR BIOHAZARDOUS MATERIALS? \_\_\_\_\_  
\_\_\_\_\_
32. ARE QUARANTINED & RELEASED RAW MATERIALS & FINISHED PRODUCTS STORED IN SEPARATE, DESIGNATED, LABELED AREAS? \_\_\_\_\_  
\_\_\_\_\_
33. ARE MATERIAL HANDLING PROCEDURES IN PLACE TO PREVENT MIX-UPS, CROSS-CONTAMINATION AND CARRY-OVER BETWEEN RUNS? \_\_\_\_\_  
\_\_\_\_\_
- A. ARE RAW MATERIAL & FINISHED PRODUCT SAMPLES RETAINED AFTER TESTING IS COMPLETED? \_\_\_\_\_  
\_\_\_\_\_
- B. IS RAW MATERIAL & FINISHED PRODUCT RELEASE TESTING DONE IN HOUSE? \_\_\_\_\_  
\_\_\_\_\_
34. PLEASE INCLUDE A COPY OF YOUR VENDOR QUALIFICATION SOP.

**LABORATORY CONTROLS**

35. ARE TEST PROCEDURES DOCUMENTED IN SOP'S, BOUND NOTEBOOKS OR STM'S, REVIEWED AND APPROVED BY APPROPRIATE PERSONNEL? \_\_\_\_\_  
\_\_\_\_\_
36. HOW ARE NEW PROCEDURES VERIFIED? \_\_\_\_\_  
\_\_\_\_\_
37. ARE THE ACCURACY, SENSITIVITY, SPECIFICITY, AND REPRODUCIBILITY OF THE TEST METHODS EMPLOYED BY THE LAB ESTABLISHED AND DOCUMENTED, I.E., VALIDATED? \_\_\_\_\_  
\_\_\_\_\_
38. ARE THERE PROCEDURES FOR PURCHASE, RECEIPT, STORAGE, HANDLING, CALIBRATION / CHARACTERIZATION AND DESTRUCTION OF REFERENCE STANDARDS?  
\_\_\_\_\_
- A. ARE THE APPROPRIATE STANDARDS AVAILABLE? \_\_\_\_\_  
\_\_\_\_\_
- B. ARE THE INVENTORY AND CERTIFICATION OF REFERENCE STANDARDS MAINTAINED? \_\_\_\_\_  
\_\_\_\_\_
39. DO CHROMATOGRAPHIC METHODS INCLUDE SYSTEM SUITABILITY TESTS? \_\_\_\_\_  
\_\_\_\_\_

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**LABORATORY CONTROLS (Continued)**

40. ARE "TIME OF USE" CALIBRATIONS PERFORMED AS APPROPRIATE, E.G., DAILY CHECK WEIGHTS ON ANALYTICAL BALANCES, pH STANDARDIZATION? \_\_\_\_\_
41. IS THERE A CHEMICAL CONTROL PROGRAM, I.E., DATE RECEIVED, DATE OPENED, DATE EXPIRED, INITIALS OF PERSON WHO OPENED? \_\_\_\_\_
42. ARE ALL CHEMICAL SUPPLIES, REAGENTS AND MEDIA LABELED TO INDICATE IDENTITY, CONCENTRATION, STORAGE AND SAFETY REQUIREMENTS, AND EXPIRATION? \_\_\_\_\_
- A. ARE THEY STORED AT MANUFACTURER- OR USP-RECOMMENDED TEMPERATURES? \_\_\_\_\_
- B. ARE THE EXPIRATION DATES REASONABLE / JUSTIFIED? \_\_\_\_\_
- C. ARE EXPIRED CHEMICALS DISPOSED OF? \_\_\_\_\_
43. FOR COMPUTERIZED SYSTEMS AND INSTRUMENTS CONTAINING DATA ACQUISITION COMPUTER SOFTWARE, HAS THE SOFTWARE BEEN VALIDATED? \_\_\_\_\_
- A. IS THERE AN SOP COVERING DATA BACKUP AND SECURITY? \_\_\_\_\_
- B. HOW IS SYSTEM ACCESS OBTAINED AND REVOKED? \_\_\_\_\_
- C. HOW IS DATA STORED AND ARCHIVED? \_\_\_\_\_
- \_\_\_\_\_
- D. HOW LONG IS DATA RETAINED? \_\_\_\_\_
- E. DOES THE SOP INCLUDE A DISASTER RECOVERY PLAN? \_\_\_\_\_
44. IS ANY TESTING SUBCONTRACTED? \_\_\_\_\_
- A. IF YES, HAS THE SUBCONTRACTOR(S) BEEN AUDITED? \_\_\_\_\_
- B. HOW ARE CLIENTS INFORMED THAT A SUBCONTRACTED LAB IS TESTING THEIR SAMPLES? \_\_\_\_\_
- \_\_\_\_\_
45. DOES THE LAB USE AN INTERNAL WATER PURIFICATION SYSTEM? \_\_\_\_\_
- A. WHAT IS THE SOURCE OF THE WATER? \_\_\_\_\_
- B. WHAT IS THE WATER USED FOR IN THE LAB, I.E., MOBILE PHASE PREPARATIONS, STANDARD PREPARATIONS, VOLUMETRIC SOLUTIONS? \_\_\_\_\_
- C. HOW OFTEN IS WATER MONITORED FOR CHEMICAL TESTING? \_\_\_\_\_
- D. FOR MICROBIOLOGICAL TESTING? \_\_\_\_\_
- E. IS THE WATER SYSTEM VALIDATED? \_\_\_\_\_
- F. HOW OFTEN RE-QUALIFIED? \_\_\_\_\_
46. IS THERE AN APPROVED SOP FOR THE OPERATION AND MAINTENANCE OF THE WATER SYSTEM? \_\_\_\_\_

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11. DO EMPLOYEES RECEIVE SPECIALIZED TRAINING IN ASEPTIC TECHNIQUE, CLEANROOM BEHAVIOR, ETC., AS APPROPRIATE? \_\_\_\_\_  
A. IS THE TRAINING DOCUMENTED? \_\_\_\_\_
12. IS THERE A ROOM FOR TESTS SUCH AS STERILITY TESTING? \_\_\_\_\_  
A. IS THE ROOM CLASSIFIED? \_\_\_\_\_  
B. WHAT IS THE CLASSIFICATION? \_\_\_\_\_  
C. HOW OFTEN ARE HEPA FILTERS CHECKED / CERTIFIED? \_\_\_\_\_  
D. ARE THE ROOMS CONTROLLED AND MONITORED FOR TEMPERATURES AND RELATIVE HUMIDITY? \_\_\_\_\_  
E. IS THERE AN SOP FOR THE CLEANING AND DISINFECTION OF THE ROOM? \_\_\_\_\_  
F. IS ENVIRONMENTAL MONITORING PERFORMED IN THE STERILITY TESTING AREA? \_\_\_\_\_  
G. WHAT IS THE FREQUENCY AND NUMBER OF AIR SAMPLES TAKEN? \_\_\_\_\_  
H. WHAT IS THE NUMBER OF SURFACE SAMPLES? \_\_\_\_\_
13. HAVE STERILITY FAILURES OCCURRED FOR ANY STERILITY TESTS? \_\_\_\_\_  
A. HAVE STERILITY FALSE POSITIVES OCCURRED? \_\_\_\_\_  
IF SO, WHAT WAS THE OUTCOME AND JUSTIFICATION FOR ANY ACTION TAKEN? \_\_\_\_\_  
\_\_\_\_\_
14. IS THE AUTOCLAVE VALIDATED? \_\_\_\_\_  
A. ARE CYCLES AND LOAD PATTERNS USED CONSISTENT WITH VALIDATION? \_\_\_\_\_  
B. IS THERE A RE-VALIDATION SCHEDULE? \_\_\_\_\_
15. ARE CLEANING PROCEDURES FOR CLASSIFIED AREAS IN PLACE? \_\_\_\_\_  
A. ARE CLEANING AGENTS ROTATED ADEQUATELY? \_\_\_\_\_  
B. ARE THE CLEANING AGENTS / DISINFECTANTS FILTERED? \_\_\_\_\_
16. ARE THERE APPROPRIATE PROCEDURES FOR GOWNING AND ACCESS TO THE LAB? \_\_\_\_\_  
A. TO THE STERILITY SUITE? \_\_\_\_\_  
B. HOW ARE OPERATORS QUALIFIED/CERTIFIED? \_\_\_\_\_  
\_\_\_\_\_

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**LABORATORY DOCUMENTATION / RECORDS AND REPORTS**

17. ARE THERE ADEQUATE PROCEDURES FOR REPORTING, REVIEWING AND ARCHIVING OF DATA? \_\_\_\_\_
18. DO LAB RECORDS INCLUDE A STATEMENT OF EACH METHOD USED IN THE TESTING OF SAMPLES? \_\_\_\_\_
- A. CAN YOU EASILY DETERMINE FOR ANY TEST REPORT, THE VERSIONS OF THE METHODS THAT WERE IN USE AT THE TIME OF TESTING? \_\_\_\_\_
19. IS THE METHOD TRACEABLE TO A VALIDATION THAT ESTABLISHES THAT THE METHOD MEETS PROPER CRITERIA, PER USP OR ICH GUIDELINES? \_\_\_\_\_
- A. IF A USP OR OTHER RECOGNIZED STANDARD METHOD IS USED, IS THE SUITABILITY OF THE METHOD VERIFIED UNDER ACTUAL CONDITIONS OF USE? \_\_\_\_\_
20. ARE THERE SOP'S DESCRIBING RECORDS FOR, AND DO THE RECORDS INCLUDE:
- A. A STATEMENT OF THE WEIGHT OR MEASURE OF THE SAMPLE USED FOR EACH TEST, WHERE APPROPRIATE? \_\_\_\_\_
- B. ALL DATA OBTAINED DURING THE TEST, INCLUDING ALL GRAPHS, CHARTS AND SPECTRA PROPERLY IDENTIFIED TO SHOW THE SPECIFIC SAMPLE AND LOT TESTED? \_\_\_\_\_
- C. IDENTIFICATION OF ALL EQUIPMENT USED? \_\_\_\_\_
- D. ALL CALCULATIONS PERFORMED IN CONNECTION WITH THE TEST, INCLUDING UNITS OF MEASURE, CONVERSION FACTORS AND EQUIVALENCY FACTORS? \_\_\_\_\_
- E. A STATEMENT OF THE RESULTS AND HOW THE RESULTS COMPARE WITH SPECIFICATIONS? \_\_\_\_\_
- F. THE INITIALS OR SIGNATURE OF THE PERSON WHO PERFORMED EACH TEST AND THE DATE(S) THE TESTS WERE PERFORMED? \_\_\_\_\_
- G. THE INITIALS OR SIGNATURE OF A SECOND PERSON SHOWING THAT THE ORIGINAL RECORDS HAVE BEEN REVIEWED FOR ACCURACY, COMPLETENESS, INCLUDING DATES TEST PERFORMED, TEST METHODS USED, INSTRUMENTATION / CALIBRATION DATES, NAME OF CHEMIST, AND COMPLIANCE WITH ANY OTHER ESTABLISHED STANDARDS? \_\_\_\_\_
- H. WHO REVIEWS AND APPROVES LAB NOTEBOOK DATA AND ASSOCIATED DATA SUCH AS CHROMATOGRAMS? \_\_\_\_\_
- I. A DESCRIPTION OF THE SAMPLE RECEIVED FOR TESTING, QUANTITY, LOT NUMBER OR OTHER DESCRIPTIVE CODE, AND DATE SAMPLE TAKEN AND/OR RECEIVED AT THE LABORATORY? \_\_\_\_\_
- J. BOUND NOTEBOOKS OR BOUND INDIVIDUALLY NUMBERED PAGES USED FOR RECORDING DATA? \_\_\_\_\_
- K. IF SO, HOW IS THE ISSUANCE AND RETRIEVAL OF BOUND NOTEBOOKS CONTROLLED AND DOCUMENTED, AND EXPLAIN HOW THE LOOSE PAGES ARE CONTROLLED? \_\_\_\_\_
- \_\_\_\_\_

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**LABORATORY DOCUMENTATION / RECORDS AND REPORTS (Continued)**

- 21. WHAT SYSTEM PREVENTS DESTRUCTION OF UNDESIRABLE DATA? \_\_\_\_\_  
\_\_\_\_\_
  
- 22. HOW LONG ARE RECORDS RETAINED? \_\_\_\_\_
  
- 23. ARE ANY DEVIATIONS FROM THE ESTABLISHED TEST METHOD DOCUMENTED, INCLUDING THE REASON FOR THE MODIFICATION AND DATA TO VERIFY THAT THE MODIFICATION PRODUCED RESULTS THAT ARE AT LEAST AS ACCURATE AND RELIABLE FOR THE MATERIAL BEING TESTED AS THE ESTABLISHED METHOD? \_\_\_\_\_  
\_\_\_\_\_
  
- 24. ARE COMPLETE RECORDS MAINTAINED OF ANY TESTING AND STANDARDIZATION OF LAB REFERENCE STANDARDS, REAGENTS AND STANDARD SOLUTIONS? \_\_\_\_\_
  
- 25. IS DOCUMENTATION, E.G., NOTEBOOKS, TEST RECORDS, FORMS, ETC., cGMP COMPLIANT FOR DATA ENTRY, ETC.? \_\_\_\_\_  
A. HOW ARE DATA SHEETS CONTROLLED? \_\_\_\_\_
  
- 26. IS THERE AN APPROVED SOP FOR HANDLING OUT-OF-SPECIFICATION (OOS) OR SUSPECT TEST RESULTS? \_\_\_\_\_  
\_\_\_\_\_
  
- A. DOES THE SOP INCLUDE A REQUIREMENT FOR A WRITTEN REPORT OF THE INVESTIGATION AND APPROPRIATE RESTRICTIONS ON RE-TESTS? \_\_\_\_\_
  
- B. ARE RESPONSIBILITIES ADEQUATELY DEFINED? \_\_\_\_\_
  
- C. DOES THE SOP PROVIDE FOR CUSTOMER NOTIFICATION IN THE EVENT OF AN OOS TEST RESULT, WHICH CANNOT BE IMMEDIATELY TRACED TO LAB ERROR, WITH A LISTING OF THE OOS RESULTS AND RESULTS OF A LAB INVESTIGATION? \_\_\_\_\_

**MANUFACTURING / ENCAPSULATION CONTROLS**

- 27. DO YOU USE ONLY RELEASED RAW MATERIALS IN MANUFACTURING OR ENCAPSULATION? \_\_\_\_\_  
\_\_\_\_\_
  
- 28. ARE PRODUCTION BATCH RECORDS USED TO DOCUMENT THE MANUFACTURING OR ENCAPSULATION PROCESS? \_\_\_\_\_  
\_\_\_\_\_
  
- A. ARE ALL WEIGHTS OF MATERIALS VERIFIED BY A 2<sup>ND</sup> PERSON? \_\_\_\_\_
  
- B. ARE COPIES OF BATCH RECORDS AVAILABLE FOR CLIENT REVIEW? \_\_\_\_\_
  
- 29. DESCRIBE YOUR METAL DETECTION PROCEDURES DURING MANUFACTURING OR ENCAPSULATION. \_\_\_\_\_  
\_\_\_\_\_  
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\_\_\_\_\_



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30. DESCRIBE YOUR SAMPLING PROTOCOL EMPLOYED DURING AN ENCAPSULATION RUN. \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

31. HOW DO YOU ACCOUNT FOR UNUSED MATERIAL? \_\_\_\_\_  
\_\_\_\_\_

32. DESCRIBE YOUR LABEL APPROVAL PROCESS INCLUDING HOW YOU ACCOUNT FOR UNUSED LABELS. \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

33. DESCRIBE THE CLEANING & SANITIZATION PROCEDURES THAT ARE EMPLOYED TO PREVENT CROSS-CONTAMINATION AND CARRY-OVER BETWEEN MANUFACTURING OR ENCAPSULATION RUNS. \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

COMMENTS:

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QUESTIONNAIRE COMPLETED BY: \_\_\_\_\_ DATE: \_\_\_\_\_