INSPECTION OF: **Date:**

Full Address of Company: Inspection type: mark all that apply external { } routine { } concise { } special { } internal { } annual { } semi-annual { } announced { } unannounced { } follow-up, re-inspection { } pre-licensing { }	Products manufactured Names of Inspectors: _____ _____ _____ _____ _____ _____	Location of production Affiliation of Inspectors: _____ _____ _____ _____ _____ _____
Department(s) being inspected _____ _____ _____ _____ _____	Date(s) of inspection: inspection From _____ To _____ Normal working hours: _____	Date of most recent previous routine (Internal or external) _____ Type: _____ _____ QA audit report #_____
Floor plans of facility available? Y { } N{ }	Airflow patterns, differential pressures, and classification of production areas indicated? Y { } N{ }	Flow patterns for personal, supplies, raw materials, product, and waste for production areas indicated? Y { } N{ }

SUMMARY OF SENIOR PERSONNEL, A: (use next of these departmental divisions are not appropriate, or for other department designations)

ADMINISTRATION Position Title	Name	
_____	_____	
_____	_____	
_____	_____	
PRODUCTION DEPARTMENT Position Title	Name	Qualifications
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
ANIMAL FACILITIES Position Title	Name	Qualifications
_____	_____	_____
_____	_____	_____
ENGINEERING / MAINTENANCE Position Title	Name	Qualifications
_____	_____	_____
_____	_____	_____
QUALITY CONTROL DEPT Position Title	Name	Qualifications
_____	_____	_____
_____	_____	_____
QUALITY ASSURANCE DEPT Position Title	Name	Qualifications
_____	_____	_____
_____	_____	_____

SUMMARY OF SENIOR PERSONNEL, B: (use for additional departments or different organizational divisions)

______________DEPARTMENT Position Title __________________________ __________________________ __________________________	Name ____________________ ____________________ ____________________	Qualifications ____________________ ____________________ ____________________
______________DEPARTMENT Position Title __________________________ __________________________ __________________________	Name ____________________ ____________________ ____________________	Qualifications ____________________ ____________________ ____________________
______________DEPARTMENT Position Title __________________________ __________________________ __________________________	Name ____________________ ____________________ ____________________	Qualifications ____________________ ____________________ ____________________
______________DEPARTMENT Position Title __________________________ __________________________ __________________________	Name ____________________ ____________________ ____________________	Qualifications ____________________ ____________________ ____________________
______________DEPARTMENT Position Title __________________________ __________________________ __________________________	Name ____________________ ____________________ ____________________	Qualifications ____________________ ____________________ ____________________
______________DEPARTMENT Position Title __________________________ __________________________ __________________________	Name ____________________ ____________________ ____________________	Qualifications ____________________ ____________________ ____________________

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Is there an organizational chart? What departments are identified? Production departments(s) _____ _____ _____ _____ Filling { } Labeling/Packaging { } Quality control { } Engineering/Maintenance { } Quality Assurance { } Receiving/Warehousing { } Shipping/Distribution { } Purchasing { } Animal Procurement/Care { }				Attach org chart, add other departments or Indicate departments different from list.
2	Are there job descriptions for key personnel? Are they appropriate to the activities of the department?				
3	Number of engineering staff____ Number sufficient? Qualifications adequate? Experience sufficient? Number of production staff____ Number sufficient? Qualifications adequate? Experience sufficient? Number of quality control staff____ Number sufficient? Qualifications adequate? Experience sufficient? Number of quality assurance staff____ Number sufficient? Qualifications adequate? Experience sufficient? Number of animal care staff____ Number sufficient? Qualifications adequate? Experience sufficient?				
4	Is there a clear separation of responsibility for production from QC?				
5	Is there a clear separation of personnel from different areas handling animals, microorganisms, and product? By written procedure?				
6	Are the names and qualifications of those responsible for approving the lot processing records registered with the NCA?				

1.0 B: Key Personnel

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Are there sufficient key personnel to supervise assigned functions? Production Filling Labeling / Packaging Quality Control Engineering Maintenance Quality Assurance Other departments: _____ _____				
2	Are they skilled/trained in fields such as biology, microbiology, chemistry, veterinary medicine, chemical or industrial engineering, etc? Engineering Production Departments9s) Filling Quality Control Quality Assurance Animal Care Other: _____				

1.0 C: Training

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Are there on the job training procedures for new employees?				
2	Are training and education records available? Are they current? Are they filed with the supervisor? Engineering/Maintenance Production Department(s) Filling Quality Control Quality Assurance Animal Care Other departments _____				
3	Does a GMP training programme exist? For new employees? Annual update for all staff? Are records maintained				
4	Is there training in containment procedures? By written procedures? Are records maintained?				

1.0 D: Personal Hygiene

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Are appropriate protective apparel required? Is there gowning SOP for production staff? For other staff entering production areas? (Engineering/Maintenance; Cleaners; QC samplers; QA auditors) For staff in the Quality Control Lab?				
2	Are staffs instructed to report health or medical problems that may have an adverse effect on the product?				
3	Is there a medical monitoring programme to ensure protection of staff and product? Vaccination where applicable? For all employees? For contractors?				
4	Do controlled entry requirements exist for: Production areas? Testing areas? Animal areas? Do procedures exist for preventing unauthorized entry into: Production areas? Storage areas? Quality control areas? Animal areas? Are the procedures in writing?				

2.0 A: General

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Is the building used for manufacturing of product suitably located and constructed, and of adequate sizes to facilitate cleaning, maintenance and proper operation?				
2	Are areas clearly defined and appropriately controlled.				
a.	For quarantine and storage of starting materials?				
b.	For storage of in-process material?				
c.	For manufacturing and processing operations?				
d.	For control and laboratory operations?				
e.	For quarantine and storage of finished products?				
f.	For holding of rejected material?				
g.	For ancillary usage, e.g. rest rooms, maintenance workshops?				
h.	For animal housing?				
3	Does the building design prevent the entry of insects, vermin and other animals?				
4	Plumbing				
a	Do adequate drains exist? Are they designed with an atmosphere break to prevent back-siphon age from sewer?				
b	Are traps being maintained to ensure adequate performance?				
5	Does the design of the facility achieve a unidirectional flow of materials, personnel, product and waste so as to avoid crossover of clean and dirty (infectious) material?				
6	Is the lighting provided adequate for the conditions necessary for the work being conducted in the area?				
7	Are facility layout drawings including mechanical, electrical and architectural kept up-to date following changes? Is re validation of facilities performed following reimbursement?				
8	Campaign production				
a.	Is the facility designed and constructed to permit production in campaigns?				
b.	Has campaign changeover been validated (effectiveness of changeover)				
c.	Is there a documented procedure for changeover that described decontamination, removal of equipment, etc?				
d.	Is there a campaigning schedule available?				

2.0 A: General continued

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
9	Do washing facilities include:				
a.	Hot and cold water?				
b.	Soap and detergent?				
c.	Clean toilet facilities that are easily accessible to working area				
d.	Clean hand drying facilities?				
10	Are the premises satisfactory with respect to:				
a.	Neatness and cleanliness				
b.	State of repair, e.g. paint work, cracks in floors, ceiling or walls, door seals, etc?				
c.	Exposed piping or electrical wiring?				
d.	Blocking of air ducts?				
e.	Equipment blocking corridors or exists?				

2.0 B: Support Systems

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Support systems, including those identified below:				
a.	Are they designed and validated to assure integrity of the characteristics of in-process material and final products?				
b.	Is there a planned maintenance program on each system? Is it followed?				
c.	Are there specs and written procedures for the operation of the systems, sampling plan, sites monitored and alert and action levels defined?				
d.	Are definitive action steps taken to resolve conditions that are out of specification?				
2	HVAC system				
a.	Are pre-filters present in heating, ventilation and air-conditioning (HVAC) systems and replaced on a routine basis?				
b.	Are high-efficiency particulate air (HEPA) filters tested for integrity, at least annually?				
c.	Are HEPA filters terminally located?				
d.	Are ductwork materials impervious to disinfectants that may cause corrosion?				
e.	Are duct work and filters located outside the clean rooms?				
f.	If fumigation procedures are used, is the facility designed to permit effective fumigation?				
g.	Is the number of air changes per hour adequate for defined areas?				
h.	Is the air flow adequate? (Minimal pressure differential (1.21mm H_2O) maintained?				
i.	Is room temperature and humidity effectively controlled?				

2.0 B: Support Systems continued

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
3	Compressed Air				
a.	Is the air supply free from oil?				
b.	Is the air supply filtered through a sterilizing grade air filter?				
c.	Is humidity controlled?				
4	Clean steam				
a.	Is clean steam used for sterilization of product contact surfaces?				
b.	Is the distribution system constructed of stainless steel treated to prevent corrosion and sloped for drainage?				
5	Water for injection (WFI) system				
a.	Is the design of the WFI system adequate to supply sufficient water of compendia (pharmacopoeial)quality?				
b.	Is there a holding tank for the WFI system, is it fitted with a sterilizing grade vent filter that is integrity tested?				
c.	If WFI is stored on a continuous circulation, is it held at $\geq$ 80°C? If not circulated, is it discarded every 24 hours or diverted for suitable use?				
d.	If WFI used as a lubricant on the recirculation pumps?				
e.	Are all the dead-legs within acceptable length?				

2.0 C: Sterile Processing

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Are the aseptic manufacturing areas and operations consisted with the WHO guidelines for sterile pharmaceutical products provided in TRS 823, Section 17, page 59ff?				
2	Does the aseptic manufacturing area include:				
a.	Smooth, hard non-particulate generating cleanable floors, walls and ceiling? Able to withstand cleaning, disinfecting reagents?				
b.	No horizontal pipes of conduits located over exposed components, in-process material, and production or product contact surfaces?				
c.	Environmental controls, e.g. temperature, humidity and viable and non-viable particles? Are there specifications for these controls? Has the system been validated?				
d.	Air supplied through HEPA filters? (Terminal filters should be employed for final formulation and filling activities)				

2.0 C: Sterile Processing, continued

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
e.	Environmental monitoring system, e.g. temperature, humidity and particulates?				
f.	Fixtures (electrical outlets and lighting, etc.) flush mounted and sealed to prevent air leakage, water access?				
g.	Identification of all pipes or conduits for air clean steam or liquids?				
h.	Properly equipped gowning area/air lock?				
i.	The ability to achieve appropriate air standards (Grade A,B,C,D) during operation?				
j.	Appropriate air flow design including segregated air systems for different aspects of the processing, e.g fermentation and filling?				
k.	Appropriate air flow design so that the area is flushed by HEPA filtered air exhausted through return ducts (not blocked by equipment)				
l.	The ability to maintain the appropriate pressure differentials between work areas with different Grades of air?				
3	Does the aseptic manufacturing area exclude:				
a.	Access doors for servicing equipment and fixtures? (should only be from outside area)				
b.	Drains?				
c.	Sinks?				
4	Is the vaccine processing area isolated and independent of any space used for any other purpose?				
5	Are the facilities appropriately designed and validated to comply with relevant containment levels assigned to organisms involved in the manufacturing process?				
6	Is the aseptic manufacturing area cleaned according to a validated procedure? Is it followed? Is the cleaning data recorded?				

3.0 A: Adequacy

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Is the equipment appropriately designed, constructed and maintained?				
2	Are steps taken to prevent any substances required for operation, such as lubricants or coolants, from coming in contact with in-process or finished products?				
3	Are equipment surfaces that contact components or products of a non-interactive nature?				
4	Are process pipelines or service lines whose contents come in contact with products or product contact surfaces sloped to allow proper drainage?				

3.0 B: Cleaning and Maintenance

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Is the equipment suitably located to facilitate its use, cleaning and maintenance?				
2	Are equipment and utensils cleaned, maintained and sanitized as appropriate to prevent malfunction or cross-contamination?				
3	Are piping systems, valves and vent filters properly designed to facilitate cleaning and sterilization? NOTE: Maintaining closed systems through the use of “clean in place” and “sterilize in place” if preferable.				
4	Are the valves on primary containment vessels (e.g. fermenter) steam sterilized?				
5	Are non-fiber releasing filters used for filtration?				
6	Are filters used for sterile filtration integrity tested before and after use?				
7	Are calibrations and validation being performed adequately?				
8	Are autoclaves and sterilizing ovens fitted with effective, proper air filters and are these integrity tested? Are HEPA filters used for the ovens?				
9	Are supplies and equipment which are exposed to pathogens during processing kept separate from unused items to prevent cross-contamination?				

3.0 C: SOPs and Records

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Are there written procedures (SOPs) for cleaning and maintenance of equipment and utensils and are they followed?				
2	Do these SOPs include:				
a.	Assignment of responsibility for cleaning?				
b.	Defined schedules for cleaning and maintenance?				
c.	Description of methods, equipment and materials used?				
d.	Instruction for protection of clean equipment from contamination?				
e.	Inspection of equipment for cleanliness immediately before use?				
f.	Assignment of identification number?				
g.	Documentation in record books?				
3	Are cleaning and sanitizing agents validated and approved for use by QC?				
4	Is clean equipment identified as such?				
5	Are calibrations and qualifications properly recorded?				
6	Are all certifications within date?				
7	Are there preventive maintenance programs and consistent records of work performed?				

3.0 D: Automated and Computerized Equipment and Systems

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	For automatic and computer-controlled systems:				
a.	Is there an adequate description of the system, the components, and the operating characteristics including a logic flow diagram?				
b.	Is there an individual with appropriate expertise in charge?				
c.	Is there a procedure for on-going evaluation and change control?				
2	Are there manual overrides for automated production equipment or facility systems in case of failure?				
3	Are the procedures in writing?				
4	Are computer systems such as programmable scales, autoclave, etc. controlled in order to prevent unauthorized changes?				
5	Are back-files of computerized data created regularly and maintained?				
6	Where computerization eliminates calculations, is a written record of the program filed with the validation data?				
7	Are there alternative systems (hard copy) designed and maintained to ensure that back-up data are exact and complete and is that system secured from alteration, erasure or loss?				
8	Validation of hardware and software:				
a.	Have all systems been validated?				
b.	Is validation performed in-house or on contract? If on contract, are records kept of the qualifications of the contractor?				
c.	Are records maintained?				
d.	Has a risk assessment of each computer system been made? It is appropriate?				

4.0 A: Adequacy of starting materials

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Are there approved specification for all starting material or raw material used in the manufacturing process and are they released by Quality control?				
2	To ensure the quality of raw materials:				
a.	Is there a quarantine and release system?				
b.	Are the conditions of storage evaluated?				
c.	Do the contracts with vendors ensure quality and stability, including reporting of changes in manufacture?				
3	For raw material of animal origin:				
a.	Are the details of source, origin, and method of manufacture documented?				
b.	Are they stored in controlled environments?				
c.	Are expiry dates given and is there a retest policy?				
d.	Are rejected materials properly segregated from acceptable material?				
e.	Have viral removal and inactivation procedures been validated?				
4	Are biological materials that may contain infectious organisms screened or tested prior to entry into laboratories or manufacturing sites?				
5	Do Master / Working Cell Banks and Seed Stocks have detailed records of:				
a.	History of cells including the number of generation doublings or passages of virus? Is there a maximum limit?				
b.	Characterization according ot the WHO TRS relevant to the product?				
c.	Demonstration of purity?				
d.	Manufacturing procedures?				
e.	Appropriate storage and security with continuous monitoring of temperature, alarms and backup power supply?				
f.	Inventory log?				
g.	Adequately segregates storage to avoid mix-up or cross-examination with other material?				
h.	Storage split into 2 separate locations?				
i.	Routine monitoring of stability (viability / purity)?				
j.	Demonstration of identify?				

4.0 B: Processes

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Master Formula (MF):				
a.	Does the MF adequately describe the complete production process?				
b.	Is the MF up-to-date and approved by QC/QA				
c.	Is the Batch Production Record form and adequate representation of the MF?				
2	Process validation:				
a.	Has each phase of the production process been validated according to an approved validation protocol?				
b.	Is re-validation done when required, and performed appropriately?				
3	Aseptic fill:				
a.	Are suitable precautions taken to maintain aseptic conditions during the filling process?				
b.	Is each filling process validated by a simulated media fill?				
c.	Does the simulation use suitable medium, fill sufficient numbers of vials, and cover the full complexity of operations?				
4	Are time and temperature limits established for the completion of production phases?				
5	Are viral removal and inactivation processes validated, if applicable?				
6	Are in-process intermediate materials tested for identity, quality strength and purity? Alternatively, are there valid certificates of quality issued from the suppliers?				
7	Is there bioburden monitoring of starting, raw, and in-process materials before sterilization?				
8	Are alert and action limits established for environmental monitoring, and are effective measures taken when limits are exceeded?				
9	Are criteria for microbial limits, physico-chemical characteristics and endotoxins established for water systems and are effective measures taken when limits are exceeded?				

4.0 C: Sterilization/Depyrogenation

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Are all sterilization/depyrogenation processes and cycles validated and current?				
2	Is there a sufficient supply of pure steam to assure the simultaneous and proper operation of the validated number of autoclaves?				
3	Are systems for filter sterilization validated and conditions still the same as when validation was performed?				
4	Is an expiry date given to sterilized items and is there a maximum time period established between washing and sterilization? Are storage conditions for sterilized items specified and appropriate?				
5	Are the filters tested immediately before and after use for integrity by an appropriate method such as the bubble point test?				
6	Are in-line sterilizing filters used for routine addition of gases, media, solutions, etc. to fermenter?				

4.0 D: Identification

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	If a component/material is transferred to a new container, is the new contained identified with:				
a.	Component/material name or item code?				
b.	Receiving or control number?				
c.	Amount in container?				
2	Are dispensing/addition operations adequately supervised in that each component /material dispensed is examined by a second person to ensure:				
a.	The component/material was released by QC?				
b.	The amount agrees with the batch record?				
c.	The container is properly identified?				
d.	The components/material are added in the batch by one person and verified by a second person?				
3	Are actual yield and percentages of theoretical yield determined at the conclusion of each phase of operation with documentation of any losses?				
4	Are the yield calculations verified by a second person?				
5	Are all containers, lines and major equipment identified at all times production for content and phase of operations?				

4.0 D: Identification, continued

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
6	Is major equipment identified with an identification number, which is recorded in the batch processing records (BPR) during production?				
7	Are all deviations from SOPs documented and subject to review by QA/QC for approval or corrective action?				
8	Are there written procedures established to specify action taken with regard to the identification and disposition of material in the environmentally controlled rooms and in the autoclave if the automatic system fails or malfunctions?				
9	Are records made of the mode, date, duration, temperature and other conditions relating to each sterilization cycle of equipment and supplies used in production? Are they maintained in a manner that permits identification of the product with the particular manufacturing and sterilization process?				
10	Are sterilized items identified by a sterilization reference number?				
11	Are inspections of areas undertaken immediately prior to use to ensure that all materials from previous operation have been removed and are these procedures?				
12	Are all autoclaved and dry heat sterilized items marked with heat sensitive indicators?				

5.0 A: Adequacy

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Are specifications, standards, sampling plans, test procedures or other laboratory control mechanisms including any revision, reviewed and approved by Quality Assurance?				
2	Are any deviations from these specs, standards, etc. recorded and justified?				
3	Do laboratory controls include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, test procedures and reference substances, designed to assure that tested materials conform to appropriate standards of identify, strength, quality and purity?				
4	Do these laboratory controls include:				
a.	Determination of compliance with written specifications for acceptance of each lot within each shipment of materials or holding or products?				
b.	Description of sampling and testing procedures for in-process materials?				
c.	Retest policy, indentifying the rationale and criteria for retests, number of samples, and the documentation required?				
d.	A comprehensive calibration program that includes calibration/certification intervals, acceptance criteria and provisions for remedial action?				
5	Are reagents, culture media, etc. properly labeled, preparation recorded in lab books and expiry dates given?				
6	Is appropriate testing done on each batch of product required to be free of objectionable microorganisms?				
7	Are there written sampling and testing plans for raw materials, intermediates, and final products that include method of sampling and the number of units per batch to be tested and are the followed?				

5.0 B: Reference Reagents

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Are all reference reagents kept secure, properly stored, identified and their integrity maintained?				
2	Are the tests results of all reference and standards analyzed at appropriate intervals for statistical variation from the expected value?				

5.0 C: Validation, Calibration and Stability Programme

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Are the accuracy, sensitivity, specificity and reproducibility of test methods established, documented, validated and subject to regular review and updating?				
2	Is there a written testing programme designated to assess the stability characteristics of each product to determine the appropriate storage conditions and expiration dates?				
3	Is there a retention sampling system?				
4	Does the retention sample quantity consist of at least twice the quantity needed to perform all required tests (except for sterility and pyrogens)?				
5	Any retention samples of each lot of final product stored under conditions consistent with product labeling?				
6	Are these samples at least visually examined annually for evidence of deterioration? Is this recorded?				

6.0 A: General

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Are there records for:				
a.	All materials used?				
b.	All standard operating procedures?				
c.	Each lot and/or batch processing and distribution?				
d.	All complaints and their investigation?				
e.	All equipment, including cleaning, maintenance and validation?				
f.	Cleaning, maintenance and environmental control of the premises?				
2	Are all records:				
a.	Dated?				
b.	Signed by the person performing the task (and, for all critical steps, by the person checking it)?				
c.	Kept at the workstation during the entire operation?				
d.	Retained and available for inspection at least 2 years after the expiry date of the lot/batch?				

6.0 B: Lot/Batch Processing Records (BPR)

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Does the BPR indicate:				
a.	The name, strength and dosage of the product?				
b.	The date of manufacture?				
c.	The lot and batch identification no.?				
d.	Assurance that the copy of the master processing record is accurate?				
e.	Changes in the master processing record approved by QA prior to starting the operation?				
f.	The complete formulation of the lot/batch?				
g.	The batch number of each component or other in-process materials and, when applicable, the sterilization number?				
h.	The SOPs used?				
i.	The yield obtained a different stage of manufacture, both actual measured values and as a percentage of the expectation?				
j.	A record of each step followed?				
k.	A record of all major equipment used?				
l.	A record of all in-process control samples taken and of the results obtained?				
m.	A sample of the label on the final container?				
n.	Identification of packaging materials, containers, closures used?				

6.0 B: Lot/Batch Processing Records (BPR), contd….

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
o.	Inspection of the processing area before and after use?				
p.	Precautions taken and special or unusual observations made throughout the manufacture of the lot?				
q.	Investigation of all unusual observations for the batch and where relevant, from samples of other batches of the product?				
r.	For rejected lots/batches, a record of disposal or reprocessing?				
2	Are all batch processing records reviewed and signed appropriately as indicated by:				
a.	A BPR review document or checklist describing the review process?				
b.	A dated signature of the person responsible for approving the manufacturing operations?				
c.	An analytical report, dated and signed by the responsible person, showing whether the lot/batch complies with the specifications?				
d.	Decision on release or rejection of the lot/batch by the quality control department?				
3	Are the BPRs maintained on file for 2 years past the expiry date?				

6.0 C: Documentation of Equipment Used

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Are records on the use, cleaning, sterilization and maintenance of equipment kept in individual logs for each piece of equipment?				
2	Are these records dated and signed in chronological order?				
3	Do the records include information of the lot/batch including identification numbers and dates?				

7.0 A: Procurement

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Are there SOPs for animal procurement?				
2	Is a specific individual in department, authorized to order animals?				
3	Do contracts with supplies assure the quality and consistency of the animals provided?				
4	If the animals come from the manufacturer's own breeding colony, are there SOPs for the maintenance and testing of the colony?				

7.0 B: Receipt and Evaluation

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Are there SOPs covering the receipt of animals, including identification of the responsible person and required documentation?				
2	Are the newly received animals placed in quarantine?				
3	Are there SOPs for evaluating the health status of animals prior to use?				

7.0 C: Care

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Are there SOPs covering housing, feeding, handling and care of the animals?				
2	Are there SOPs for identification and isolation of any sick animal?				
3	Are any sicknesses of animals, treatment and preventive measures recorded?				

7.0 D: Allocation of Animals to Use

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Are the specifications for animals used in production or quality control tests written in the respective SOPs?				
2	Is there a clear system of identification of animals allocated for each test or use?				

7.0 E: Facilities

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Are there enough animal rooms of appropriate design to allow separate housing of:				
a.	The breeding colony?				
b.	Different animal species?				
c.	Animals in quarantine?				
d.	Sick animals?				
e.	Animals on-test including tests with hazardous infectious and non-infectious materials?				
2	Are there facilities and SOPs for collection and disposal of animal waste and of dead animals, to minimize disease hazards and environmental contamination?				
3	Are there facilities and SOPs for cleaning, sanitizing, sterilizing and maintaining supplies and equipment including animal cages and racks?				
4	Are there specially designated areas for animal inoculation and sample taking, aseptic surgery, autopsy, radiography, histology and other laboratory tests?				
5	Are there separate storage areas for equipment, animal feed and bedding which are protected from infection/contamination, and with refrigeration where needed?				
6	I equipment suitably located for operation, inspection, cleaning and maintenance?				
7	Is there separate space for locker, shower, toilet and washing facilities for staff working in the animal facilities?				
8	Is there an appropriate functioning environmental control system?				
9	Is there an implemented pest control system that is documented, validated and approved by QA showing absence of interference with the tests and maintaining animal welfare?				
10	Is the HVAC system appropriate with temperature and humidity control, and adequate air changes/hour?				
11	Is there a time-controlled lighting system?				
12	Is there an appropriate noise control system?				
13	Is emergency power available in the event of a power failure?				

8.0 A: General

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Are there records on suppliers, contractors and consultants?				
2	Are there records of their qualifications?				
3	Are there records on up-dating documents?				

8.0 B: SOPs

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Are there SOPs written and approved for all manufacturing and testing activities?				
2	Are the SOPs reviewed on a regular and defined schedule? At least annually?				
3	Are revisions of SOPs approved by an authorized person?				
4	Is there a system for distribution of SOPs and for revocation of outdated SOPs?				
5	Is it clear that SOPs are used and followed in both production and QC?				

8.0 C: Equipment

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Is there a system for validation and regular revalidation of all equipment, including revalidation after repairs?				
2	Is there a system for calibration of all instruments?				
3	Is there a system to report, investigate and record all deviations from specifications or malfunctioning of equipment?				

8.0 D: Environmental Monitoring

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Is there monitoring of air for microbes?				
2	Is thee monitoring of air for particulates?				
3	Is there monitoring of surfaces for microbes?				
4	Is there monitoring of compressed gas for particulates?				
5	Is there monitoring of compressed gas for particulates?				
6	Is there monitoring of water for microbes and endotoxins?				
7	Is there a defined schedule for environmental monitoring? Is is appropriate to each stage of the production process? Do the records indicate the schedule is followed?				

8.0 E: Intermediates and final product

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Is the stability of the final products and, if applicable, of the intermediates monitored?				
2	Is there a quarantine and release system for intermediates and final products, including clear identification of the status (Quarantine, released, rejected, etc.)?				
3	Is there a system for reprocessing of unsatisfactory and returned products, subject to prior approval by quality control?				
4	Is there a system for rapid evaluation and investigation of complaints received from the field?				
5	Is there a system for rapid and effective recall of products? Is there provision for the notification of the national control authority (NCA)?				

8.0 F: Quality Control

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Is the QC department independent from production?				
2	Are all QC tests validated?				
3	Does the QC laboratory have SOPs describing sampling, testing, documentation and précised criteria for release?				
4	Is QC monitoring consistency of production using trend analysis?				
5	Is the QC Laboratory involved in all decisions that may concern the quality of the product?				

8.0 G: Inspections

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Is there a system for regular self-inspection of each manufacturing and test area?				
2	Are the inspections followed up to ensure that appropriate action was taken to correct deficiencies?				
3	Following the national control authority's (NCA) inspection of the manufacturer, is there a system to follow up any recommendations received from NCA?				
4	Is there a system for inspection of contractors in respect of any manufacturing or testing activities contracted out?				

9.0 A: Packaging Materials

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Do primary and printed packaging materials have specifications describing qualitative and quantitative requirements?				
2	Are standard operating procedures for the receipt, sampling and testing of packaging materials available?				
3	Are incoming materials stored in controlled areas until released from quarantine?				
4	Are released materials secured in controlled areas and is inventory maintained?				
5	Are control or reference numbers assigned to each lot for traceability and control purposes?				
6	Are all label texts approved by the national control authority prior to use and is there a master file of approved labeling held by the responsible person?				

9.0 B: Labeling and Packaging Operations

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Are SOPs available for the labeling and packaging operations for equipment and material delivery to the floor and are these easily accessible to the operators?				
2	Are labeling and packaging operations properly physically segregated to prevent mix-up of product or packaging materials?				
3	Is reconciliation performed to ascertain the number of labels issued, used and, if applicable, returned to stock? Is the data recorded on the packaging batch records?				
4	Is there a specification for permissible reconciliation limits and action to be taken in the event of exceeding these?				
5	Is all labeled product accounted for including those destroyed during and at the completion of the operation?				
6	Is there an inspection of the line made before and after each labeling and packaging operation? Is it documented and signed by the responsible person?				
7	Is the name, strength and batch number prominently displayed at each operation?				
8	Is there adequate on-line control of the labeled or packaged product including the quality of printed text?				
9	Are the pieces of equipment used during labeling operations calibrated and certified as operating correctly before and during labeling operations?				
10	Are there documented time and temperature limitations for the labeling and packaging operations?				
11	Are incidents and deviations recorded and appropriate QA actions taken?				
12	Is there a quality control mechanism for assigning lot numbers and expiry dating prior to labeling operations?				
13	Are samples of printed labels and packaging materials used for the batch kept with the records?				
14	Is there a segregated and secure quarantine storage area for finished goods awaiting QC release?				

9.0 C: Storage and Distribution

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Do records allow rapid identification of all customers who have received any amount of an identified lot/batch?				
2	Are records kept on the time, temperature and other conditions of storage before distribution?				
3	Do records show the date, quantity, and mode of package and dispatch of each lot/batch to the customer?				
4	Are there standard operating procedures for the storage of released finished product to the dispatch area?				
5	Are standard procedures available for warehousing?				
6	Are standard procedures available that describe the shipping, final transit conditions and instruction for storage through the distribution chain, especially the cold chain?				
7	Are the shipping methods, especially the cold chain, validated and routinely monitored?				
8	Are records detailed and retrievable so that a rapid recall of any particular lot is achievable? Is the recall process delegated to the responsible person?				
9	Are records maintained for 2 years after the expiry dates?				

10.0 A: Facility design

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Is their air handling system capable of maintaining the designed containment level (e.g. are supply and exhaust systems adequate for the level of containment required)				
2	Where applicable, are HEPA filters installed in the exhaust system?				
3	Can the HEPA filters be tested in situ				
4	Is the air pressure in the manufacturing area appropriate to the surrounding areas?				
5	Are the rooms designed to permit satisfactory cleaning and decontamination?				
6	If the procedure requires the availability of a wash sink, is it close to the exit of room?				
7	Are all conduits, piping and ductwork properly sealed in the area to maintain containment?				
8	Are all liquid and gas services protected by backflow prevention devices to prevent contamination?				
9	Are all traps protecting drains maintained properly?				

10.0 B: Equipment

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Is the primary containment equipment designed to limit or prevent contact between operators and microorganisms?				
2	Is the equipment designed, constructed and installed to permit ease of decontamination and cleaning?				
3	Are the appropriate classes of biosafety cabinets used for the relevant microorganisms, and are they certified annually?				
4	Is the process equipment designed to minimize aerosol generation (including sampling devices)?				

10.0 B: Equipment, contd….

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
5	Is the process equipment designed to contain organisms within a closed system (e.g. fermenter or other culture vessels)? Are seals and mechanical devices associated with the equipment designed to prevent leakage and do exhaust gases pass through HEPA filtration and/or incineration?				
6	Is the process equipment capable of being decontaminated using a validated inactivation procedure?				

10.0 C: Operational Practices and Procedures

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Are there standard operating procedures for decontamination of process equipment and facilities? Have these procedures been validated and is the performance monitored?				
2	Is the equipment tested regularly for integrity of containment capability?				
3	Are standard operating procedures available and displayed outlining emergency procedures in the event of a spill or accidental release of contaminate?				
4	Is there a list displayed of responsible individuals to be contacted in the event of an emergency?				
5	Do personnel have specific training in the procedures for handling the pathogenic agents used and the method of using containment equipment?				
6	Are there SOPs for dress codes specified for containment levels applicable and is access controlled and secured? Is there a list displayed of authorized staff for entry?				
7	Are showers available where applicable?				
8	Is there a health and medical surveillance program?				
9	Are biohazard signs used and posted where applicable?				
10	Are SOPs available for the transport of microorganisms in closed systems or containers to and from the area?				

11.0 A: General

#	Audit Item	Yes	No	NA	Observations (indicate N.O. if not observed)
1	Pest control programme:				
a.	Is there a pest control programme? Is it in writing and is it followed?				
b.	Are pesticides used?				
c.	Is their use controlled so as to avoid product contamination?				
d.	Are there records of pesticide usage?				
e.	Is pesticide storage controlled?				
f.	Has QA approved the pesticides and the programme?				
2	Are sewage, refuse, trash controlled and/or disposed of in a safe, timely and sanitary manner?				
3	Are adequately constructed waste containers located in appropriate areas?				
4	Are bagged/boxed items stored off the floors and spaced to allow for cleaning and proper identification?				
5	Do written procedures for cleaning and sanitation include:				
a.	Assignment of responsibility for sanitation?				
b.	Details of cleaning schedules, methods, equipment and material?				
c.	Routine evaluation of the effectiveness of disinfectants and cleaning agents, and chronological record of the agents used?				
d.	Information to be recorded?				
e.	Validation for effectiveness of cleaning/sanitation, and validation of removal of residual cleaning/sanitizing agents?				
f.	Are the procedures followed and are records maintained?				
6	Are equipment and chemicals used in cleaning appropriately maintained and stored?				