SAFC®

Quality Information
Buchs Manufacturing Site

Version 1 - August 1, 2010

SAFC®

Inspiring Science™

The SAFC Buchs facility adapts its supply chain and quality management systems to support your raw materials supply for industrial use

Our Buchs facility is a major center of innovation and supply chain services, where product management and R&D teams launch hundreds of new products every year with a strong focus on analytical applications. They serve our customers in the research area and provide an internal pipeline supplying raw materials for our customers with industrial applications.

Buchs provides procurement, manufacturing, quality control, packaging, quality assurance and customization beyond expectation. This creates a supply chain designed to serve the needs of industry customers for SAFC and power the research and development business.

SAFC is the custom manufacturing unit of Sigma-Aldrich® and has 30 manufacturing sites worldwide. The Buchs manufacturing center is located in the Swiss Alpes and encompasses 402,400 ft^2 (122 651m^2) of manufacturing space, certified ISO 9001:2008.

View the following supplementary documents online:

1. Quality management capabilities
2. cGMP certificate
3. ISO 9001:2008 certificate
4. Environmental protection, health and safety policy
5. Global citizenship report
6. Batch numbering system
7. Shelf-life statement
8. Product-dating-information statement
9. Shipping and long-term storage conditions document
10. Specification and Certificate of Analysis
11. Contact information

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1. Quality Management

1.1 Principles

1.1.1 Does SAFC establish, document and implement an effective system for managing quality that involves the active participation of management and appropriate manufacturing personnel? Yes. SAFC has implemented a comprehensive management system certified ISO 9001:2008 that covers all activities performed in the Swiss production facility. Click here to download more information on our management system.

1.1.2 Does SAFC have quality units that fulfill both Quality Assurance (QA) and Quality Control (QC) responsibilities? Yes. They exist as separate QA and QC units.

1.1.3 Is QC independent from production? Yes. For more details, download our organization chart.

1.1.4 Does SAFC employ qualified personnel authorized to release products? Yes. For each product a qualified person in QC or QA is responsible for release/rejection of lots.

1.1.5 Do procedures exist for notifying management in a timely manner of regulatory inspections, serious GMP deficiencies, product defects and related actions (such as quality related complaints, recalls, regulatory actions etc.)? Yes. During the regular management review meetings all quality related aspects are addressed.

1.2 Responsibilities of the Quality Units

1.2.1 Are the quality units involved in all quality related matters? Yes. The quality units are appropriately involved in all decisions. All documents in the management system are reviewed and approved by QA.

1.2.2 What is the role of the quality unit? Releases / rejections all products and raw materials.

1.2.3 Does SAFC perform internal audits? Yes, according to an internal schedule the following audits are performed:

- ISO 9001- performed by QA: > 10/year
- GMP where appropriate: > 10/year
- Safety audits: > 100/year

1.2.4 Does SAFC have procedures to ensure that quality related complaints are investigated and resolved? Yes. All quality complaints are recorded, investigated and assessed by qualified personnel in QC/QA. Actions are dated and responsibilities are defined and managed in a database. Follow-up and reporting to management is done by QA.

1.2.5 Are materials appropriately tested and the results reported? Yes. All products are tested against predefined specifications.

1.3 Responsibilities of the Production Units

1.3.1 Does SAFC make sure that necessary calibrations are performed and records kept? Yes. All critical measuring devices are appropriately qualified and regularly calibrated.

1.3.2 Does SAFC make sure that the premises and equipment are maintained and records kept? Yes. A comprehensive preventive maintenance plan is defined and managed through a state-of-the-art software application.

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1.3.3 Does the quality unit make sure that all activities are performed following pre-approved instructions? Yes. An SOP[1] is in place requiring all production activities to be performed following pre-approved instructions.

1.3.4 Does the quality unit assure that all deviations from pre-approved instructions are appropriately recorded and investigated? Yes. An SOP defines actions to be performed in case of deviation from pre-approved instructions.

1.4 Internal Audits (Self Inspection)

1.4.1 Are internal audits performed in accordance with an approved schedule in order to verify compliance with the principles of the product quality requirements? Yes, according to an internal schedule the following audits are performed:

- ISO 9001- performed by QA: > 10/year
- GMP where appropriate: > 10/year
- Safety audits: > 100/year

1.4.2 Are audit findings and corrective actions documented and brought to the attention of management? Yes. The audit findings and corrective actions are managed through our CAPA[2] system, recorded in our database and regularly reported to management.

1.4.3 Are the agreed corrective actions completed in a timely and effective manner? Yes. Regular review of all CAPA is done by QA and deviations from timelines are reported to management.

1.5 Product Quality Review

1.5.1 Are product quality reviews performed on a regular basis? Yes. Product quality reviews are performed by QA in charge of product release. This is done based on the data in our LIMS[3]-systems and not formally recorded.

2. Personnel

2.1 Qualifications

2.1.1 Is an adequate number of personnel qualified by appropriate education, training and/or experience to perform and supervise the manufacture of products? Yes. Approximately 20% of our employees hold a scientific university degree. A training program is set up to ensure continued qualification of all employees.

2.1.2 Does SAFC keep records of the trainings? Yes.

2.1.3 Is efficiency of training regularly checked? Yes, as appropriate. Usually the employee assessment is done by superiors. For some assessments, tools like multiple choice tests are used.

2.1.4 Does SAFC have documented goals concerning work safety? Yes, an EHS[4] policy exists.

2.1.5 Does SAFC perform risk analyses? Yes.

2.1.6 Does SAFC perform analyses on accidents? Yes, to learn more, download our Global Citizenship Environmental Protection, Health and Safety Policy.

[1] SOP: standard operating procedure, [2] CAPA: corrective and preventive action plan,
[3] LIMS: laboratory information and management system, [4] EHS: environmental, health and safety

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2.2 Hygiene

2.2.1 Does SAFC have a hygiene plan for personnel and facilities? Yes. Personnel receive protective work clothes to avoid direct contact with chemicals. Eating, drinking and smoking is prohibited in all production areas. Personnel with infectious diseases or open lesions are excluded from direct contact with products.

2.2.2 Is medical check for workers obligatory? Yes.

3. Buildings and Facilities

3.1 Design and construction

3.1.1 Are the facilities designed to adequately prevent contamination, cross-contamination, mix-ups? Yes.

3.1.2 Are defined areas or other control systems provided for the following activities:

- Storage of released materials? Yes.
- Production operations? Yes.
- Packaging and labeling operations? Yes.
- Laboratory operations? Yes.

3.1.3 Are adequate, clean washing and toilet facilities provided for personnel, equipped with hot and cold water as appropriate, soap or detergent, air driers or single-service towels? Yes.

3.1.4 Are the washing and toilet facilities separate from, but easily accessible to, manufacturing areas? Yes.

3.1.5 Are adequate facilities for showering and/or changing clothes provided? Yes.

3.2 Utilities

3.2.1 Does SAFC take appropriate measures to control risks of contamination and cross-contamination concerning the HVAC[1] systems? Yes. The air is filtered and not recirculated.

3.2.2 Does SAFC ensure that drains are of adequate size and are provided with an air break or a suitable device to prevent back siphonage? Yes, where appropriate.

3.3 Water

3.3.1 Does process water at SAFC meet, at a minimum, World Health Organization guidelines for drinking (potable) water quality? Yes. Various qualities of water are available. In our production facility, water is purified according to Ph Eur/USP guildlines. The water is produced in a double RO[2] system and has been validated.

3.4 Containment

3.4.1 Does SAFC produce highly sensitizing materials such as penicillines or cephalosporins? No. In our production facilities no highly sensitizing materials are produced. In our filling department (segregated building) highly sensitizing materials are handled using appropriate containment technologies.

[1] HVAC: heating, ventilating and air conditioning, [2]RO: reverse osmoses

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3.5 Lightning

3.5.1 Is adequate lightning provided in all areas to facilitate cleaning, maintenance and proper operations? Yes.

3.6 Sewage and Refuse

3.6.1 How does the site dispose of sewage, refuse and other waste (e.g. solid, liquid or gaseous by-products from manufacturing) in and from buildings and the immediate surrounding area? Waste is disposed of in a safe, timely and sanitary manner. Containers and/or pipes for waste materials are clearly labeled in order to identify and avoid mistakes. Industrial waste water is cleaned in our waste water treatment plant.

3.7 Sanitation and Maintenance

3.7.1 Are manufacturing buildings properly maintained and repaired and kept in a clean condition? Yes. All buildings and facilities are part of our preventive maintenance program. Cleaning programs are defined for all areas.

4. Equipment

4.1 Identification

4.1.1 Is equipment built so that when in contact with raw materials or products it does not alter their quality? Yes.

4.1.2 Are the big equipment (e.g. reactors, storage containers) and permanently installed product processing lines, appropriately identified? Yes.

4.2 Maintenance and Cleaning

4.2.1 Are schedules and procedures (including assignment of responsibility) established for the preventive maintenance of equipment. Yes. Preventive maintenance plans are defined for all pieces of equipment.

4.2.2 Is non-dedicated equipment for production of different materials cleaned to prevent cross-contamination? Yes. Specific cleaning procedures are in place for the various types of equipment and product changeover.

4.2.3 Are the production facilities and equipment cleaned according to written procedures? Yes.

4.2.4 Is the cleaning recorded and records kept? Yes.

4.2.5 Is the cleaning success verified by appropriate means? Yes. Standard techniques are visual assessment and specific and unspecific tests on the last rinse or swab samples.

4.2.6 Is the use of cleaning agents regulated in writing? Yes. The type and amount of cleaning agents is defined in SOPs.

4.3 Calibration

4.3.1 Is there a program in place to calibrate control, weighing, measuring, monitoring and testing of equipment in order to ensure product quality? Yes. Critical devices are defined in the maintenance program and calibrated following a predefined schedule and written calibration protocols.

4.3.2 Are equipment calibrations performed according to certified standards? Yes.

4.3.3 Are the calibration records kept? Yes.

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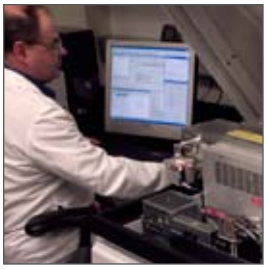

4.4 Computerized Systems

4.4.1 Is there a list of computerized systems available? Yes.

4.4.2 Are the computerized systems validated? Yes, as appropriate. A list of quality critical systems are identified and validated.

4.4.3 Are changes to the critical quality computerized systems made according to a change procedure and formally authorized, documented and tested? Yes.

4.4.4 Does SAFC keep records of all changes, including modifications and enhancements made to the hardware, software and any other critical component of the system? Yes.

4.4.5 Do these records demonstrate that the system is maintained in a validated state? Yes, change control on critical computerized systems is applied.

4.4.6 Is data recorded by a second means in addition to the computer system? Yes, as appropriate.

4.4.7 Are the systems provided with a user/access authorization? Yes.

4.4.8 Are the systems provided with audit trails? Yes, validated computerized systems have an audit trail.

4.4.9 Is the security of the stored/archived data maintained? Yes, backup is performed regularly and stored in a secure place outside the company.

4.4.9 Does SAFC use electronic signatures in its systems? Yes, electronic signatures are used in the non-GMP environment.

5. Documents and Records

5.1 Documentation System and Specifications

5.1.1 Is the issuance, revision, superseding and withdrawal of all documents controlled with maintenance of revision histories? Yes.

5.1.2 Does SAFC have procedures established for retaining all appropriate documents (e.g. development history, scale-up, technical transfer and process validation reports; training, production, control, and distribution records)? Yes.

5.1.3 Is the retention period for these documents specified? Yes.

5.1.4 What is the retention time for batch records? Batch records (production and analytical) are kept for a minimum period of 10 years.

5.2 Equipment Cleaning and Use Log

5.2.1 Are log books kept, listing the equipment history and the applied cleaning procedures (chemical log)? Yes.

5.2.2 Are log books kept, listing all maintenance and repair work (technical log)? Yes.

5.3 Records of Raw Materials, Intermediates, Labeling and Packaging Materials

5.3.1 Is traceability of production and filling raw materials guaranteed? Yes, all raw materials used are traceable, as the used lot numbers are recorded in the batch records.

5.3.2 Does SAFC keep sample labels for each filling operation? Yes.

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5.4 Master Production Instructions (Master Production and Control Records)

5.4.1 Does SAFC produce products following written and approved procedures? Yes, for most of our products written approved master batch records are available to ensure uniformity from batch to batch. Exceptions are made for products from our innovation laboratories, which are produced in lab scale. These are recorded in laboratory notebooks, often following procedures from literature.

5.5 Batch Production Records

5.5.1 Are production runs recorded by means of batch production records? Yes. All relevant parameters of the batch are recorded in those records.

5.6 Laboratory Controls

5.6.1 Is all relevant information on QC-testing recorded? Yes. The laboratory records include complete test data to ensure compliance with established specifications and standards, including examinations and assays.

5.7 Batch Production Record Review

5.7.1 Are the production batch records reviewed by qualified personnel before release of a batch? Yes. A SOP defines the appropriate functions qualified for the batch record review, as well as the scope of the review.

6. Material Management

6.1 General Controls

6.1.1 Does SAFC purchase the materials against an agreed specification from a supplier approved by the quality unit? Yes. All materials are purchased from qualified vendors. New vendors, since 2004, are qualified using quality questionnaires.

6.2 Receipt and Quarantine

6.2.1 Are containers examined visually for correct labeling upon receipt and before acceptance (including correlation between the name used by the supplier and the in-house name, if these are different), container damage, broken seals and evidence of tampering or contamination? Yes.

6.2.2 Are these materials held under quarantine until they have been sampled, examined or tested as appropriate and then released for use? Yes.

6.2.3 Is each container or grouping of material containers (batches) assigned and identified with a distinctive code, batch or receipt number? Yes.

6.2.4 Is this number used in recording the disposition of each batch? Yes.

6.2.5 Can SAFC identify the status of each batch? Yes. A unique batch number is assigned to every received vendor lot. The materials can be traced throughout its life cycle in the SAP system.

6.3 Sampling and Testing of Incoming Production Materials

6.3.1 Does SAFC conduct at least one test to verify the identity of each batch of material? Yes.

6.3.2 Does SAFC take representative batch samples? Yes.

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6.3.3 Do the sampling methods specify the number of containers to be sampled, which part of the container to sample and the amount of material to be taken from each container? Yes, according to the sampling plan laid down in the LIMS system.

6.3.4 Is the sampling conducted at defined locations and by procedures designed to prevent contamination and cross-contamination of the material sampled? Yes. A dedicated sampling area in our goods receipt is used. The sampling group is part of our QC department.

6.4 Storage

6.4.1 Is material handled and stored so to prevent degradation, contamination and cross-contamination? Yes. Appropriate storage facilities are available for all types of chemicals handled on site.

6.4.2 Does SAFC assure that materials stored off-the-floor in fibre drums, bags or boxes are suitably spaced to permit cleaning and inspection? Yes.

6.4.3 Does SAFC ensure that labels of containers stored outdoors remain legible and that containers are appropriately cleaned before opening and use? N/A. All storage areas outdoors are roofed buildings.

6.4.4 Does SAFC identify and control rejected materials under a quarantine system, designed to prevent their unauthorized use in manufacturing? Yes. Blocked materials are not available for transportation. This is guaranteed by the SAP warehouse management system.

6.5 Re-evaluation

6.5.1 Are materials re-evaluated as appropriate to determine their suitability for use (e.g. after prolonged storage or exposure to heat or humidity)? Yes. Retest periods are defined for all materials in our LIMS system. Tests are triggered by the system automatically.

7. Production and In-Process Controls

7.1 Production Operations

7.1.1 Are raw materials weighed or measured under appropriate conditions so it does not affect their suitability for use? Yes.

7.1.2 Does SAFC ensure that if a material is subdivided for later use in production operations, the container receiving the material is suitable and identified to reflect the following information:

- Material name and/or item code? Yes.
- Receiving or control number? Yes.
- Weight or measure of material in the new container? Yes.
- Re-evaluation or retest date if appropriate? Yes.

7.2 Time Limits

7.2.1 Are time limits for specific production activities defined in the master production instructions? Yes.

7.3 In-process Sampling and Controls

7.3.1 Are written procedures established to monitor the progress and control the performance that cause variability in quality characteristics? Yes.

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7.3.2 Are in-process controls and their acceptance criteria defined based on the information gained during the development stage or historical data? Yes. In-process controls are performed as defined in the development reports and based on experience from previous production runs.

7.3.3 Do the acceptance criteria and extent of testing depend on the nature of the manufactured product, the reaction or process step and the degree to which the process introduces variability in the product quality? Yes.

7.3.4 Are there written procedures describing sampling methods for in-process materials? Yes.

7.3.5 Are the sampling plans and procedures based on scientifically sound sampling practices? Yes. Methods and sampling plans are defined in the master batch record and in the LIMS system.

7.3.6 Is process sampling conducted using procedures designed to prevent contamination of the sampled material? Yes.

7.3.7 Are procedures established to ensure the integrity of samples after collection? Yes. A detailed SOP and additional instructions in the master match records describe the process of in-process sampling.

7.4 Blending Batches

7.4.1 Are OOS[1] batches blended with in-specification batches for the purpose of bringing OOS material into specification? No.

7.4.2 Is blending of batches conducted in order to increase batch size? Yes, as appropriate. Only batches meeting the specifications are blended.

7.5 Contamination Control

7.5.1 Are production operations conducted in a manner that will prevent contamination of products by other materials? Yes.

8. Packaging and Product Identification

8.1 General

8.1.1 Are products packaged and labeled following written procedures? Yes.

8.2 Packaging Materials

8.2.1 Are products packaged in predefined containers which provide adequate protection against deterioration or contamination that may occur during transportation and recommended storage? Yes. Containers are defined according to our vast experience with chemicals and in accordance with the shipping regulations.

8.3 Label Issuance Control

8.3.1 Do procedures exist to reconcile the number of labels issued, used and returned and to evaluate discrepancies between the number of containers labeled and the number of labels issued? Yes. Label reconciliation is part of the manufacturing process and deviations are investigated appropriately.

[1] OOS: out of specification

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8.4 Packaging and Labeling Operations

8.4.1 Are there procedures to guarantee correct packaging materials? Yes. The packaging material is defined in the bill of material issued with the packaging forms.

8.4.2 Are there procedures to ensure correct labels? Yes. The labels are identified by a unique label identification number which is referenced in the bill of material. The printed labels are additionally checked against the information on the product and the work order.

8.4.3 Are there procedures to prevent mix-ups during packaging and labeling operations? Yes. All materials and operations are appropriately segregated.

8.4.4 Are records kept for packaging and labeling operations? Yes.

9. Storage and Distribution

9.1 Warehousing Procedures

9.1.1 Are facilities available for the storage of all materials under appropriate conditions (e.g. controlled temperature and humidity when necessary)? Yes.

9.1.2 Are records maintained of storage conditions if they are critical for the maintenance of material characteristics? Yes. SAP assigns the storage location based on recommended storage condition.

9.2 Distribution Procedures

9.2.1 Does SAFC ensure that products are only released for distribution to third parties after they have been released by the quality unit? Yes. Shipment of blocked stock is not possible. Release of not fully tested or OOS material against a written authorization by a customer is possible.

9.2.2 Are products transported in a manner that does not adversely affect their quality? Yes. Shipping instructions laid down in SAP assure that the product specific requirements are met.

9.2.3 Are special transport or storage conditions stated on the label? Yes.

9.2.4 Does SAFC ensure that the transporter knows and follows the appropriate transport and storage conditions? Yes.

10. Laboratory Controls

10.1 General Controls

10.1.1 Does personnel use documented procedures describing sampling, testing, approval or rejection of materials, recording and storage of laboratory data? Yes.

10.1.2 Does SAFC ensure that reagents and standard solutions are prepared and labeled following written procedures? Yes.

10.1.3 Are “use-up” dates applied as appropriate for analytical reagents or standard solutions? Yes.

10.1.4 Are primary reference standards obtained as appropriate for manufacture? Yes.

10.1.5 Is the source of each primary reference standard documented? Yes.

10.1.6 Are records maintained of each primary reference standard and use in accordance with the suppliers' recommendations? Yes, if appropriate.

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10.1.7 Are secondary reference standards appropriately prepared, identified, tested, approved and stored? Yes.

10.1.8 Is the suitability of each batch of secondary reference standard determined prior to first use by comparing against a primary reference standard? Yes.

10.1.9 Is each batch of secondary reference standard periodically requalified in accordance with a written protocol? Yes, as appropriate.

10.2 Product Testing

10.2.1 Are appropriate laboratory tests conducted to determine conformance to specifications? Yes.

10.2.2 Does SAFC establish impurity profiles for research grade products? No.

10.2.3 Are the standard research grade materials regularly tested for bioburden? Only if specified in the product specification.

10.3 Certificates of Analysis

10.3.1 Is a procedure in place defining the creation, content and release of Certificates of Analysis? Yes.

10.3.2 Are certificates dated and signed by authorized personnel of the quality unit and show name, address and telephone number of the original releasing site? Yes.

10.3.3 Are Certificates of Analysis available for all lots of products? Yes. Click to download the certificates.

10.4 Stability Monitoring

10.4.1 Is a program in place to establish stability data to support expiry/retest dates for standard research products? Yes. Regular retesting of material on stock provides adequate data for the assignment of retest/expiry date as appropriate.

10.4.2 Are stability trials conducted following GMP/ICH guidelines? Only for a limited number of products.

10.5 Expiry and Retest Dating

10.5.1 Can SAFC establish stability data to support expiry/retest dates for standard research products? Yes. Regular retesting of material on stock provides adequate data for the assignment of retest/expiry date (as appropriate).

11. Product Validation

11.1 Does SAFC have a defined philosophy concerning validation activities? Yes. A validation master plan is available.

11.2 Are production processes for standard research materials validated? Yes, as appropriate. The validation process for standard research chemicals uses a non-formalistic life cycle approach beginning from the first batches produced in our innovation labs through scale-up and later full scale production runs. Validation according to ICH/GMP guidelines is performed for APIs.

11.3 Are analytical methods validated? Yes, as appropriate. All methods are thoroughly tested during the new product design process before it is applied as release test. Validation according to ICH/GMP guidelines is performed for APIs.

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12. Change Control

12.1 Is a change control system defined to prevent unauthorized changes to established procedures? Yes, all changes are appropriately assessed and approved by qualified personnel.

13. Rejection and Re-use of Materials

13.1 Quarantine

13.1.1 Are products failing to meet established specifications quarantined and the final disposition of the materials recorded? Yes.

13.2 Reprocessing

13.2.1 Are materials being reprocessed? Yes, if necessary.

13.3 Reworking

13.3.1 Are materials being reworked? Yes, if they do not meet specifications.

13.4 Recovery of Materials and Solvents

13.4.1 Is it common practice to recover solvents and other materials for further use in production operations? No.

13.5 Returns

13.5.1 Are returned materials appropriately identified, checked for integrity and records kept concerning the final disposition? Yes.

13.5.2 Is the final disposition of returned products approved by the quality unit? Yes.

14. Complaints and Recalls

14.1 Does SAFC record and investigate all quality related complaints, whether received orally or in writing, according to a written procedure? Yes.

14.2 Do the complaint records include:

- Name and address of complainant? Yes.
- Name (and where appropriate, title) and phone number of person submitting the complaint? Yes.
- Complaint nature (including name and batch number of the product)? Yes.
- Date of when complaint is received? Yes.
- Action initially taken (including dates and identity of person taking the action)? Yes.
- Any follow-up action taken? Yes.
- Response provided to the originator of complaint (including date response sent and final decision on product)? Yes.

14.3 Are records of complaints retained in order to evaluate trends, product related frequencies and severity with view on taking additional, and if appropriate, immediate corrective action? Yes. Trending on complaints and management reporting is the responsibility of quality assurance.

14.4 Is a written procedure established that defines the circumstances under which a recall of a product should be considered? Yes. In all cases where the safety of customers/patients could be affected.

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14.5 Does the recall procedure designate who should be involved in evaluating the information, how a recall should be initiated, who should be informed about the recall and how the recalled material should be treated? Yes.

14.6 Does SAFC ensure that in the event of a serious or potentially life threatening situation, local, national and/or international authorities are informed and their advice sought? Yes.

15. Contract Manufacturers (Including Laboratories)

15.1 Are contract laboratories and contract manufacturers appropriately qualified? Yes.

15.2 Is there a list available of all contract manufacturers, including contract laboratories, which are used for quality critical activities? Yes, for all GMP relevant contractors.

15.3 Are quality agreements in place for the quality critical contract manufacturers, including contract laboratories? Yes, contracts are signed with all GMP relevant contractors.

16. Agents, Brokers, Traders, Distributors, Re-packers & Re-labelers

16.1 Applicability

16.1.1 Does SAFC produce all products offered? Over 46,000 raw materials are produced in-house out of the 100,000 offered in total.

16.2 Traceability of Distributed Products

16.2.1 Is traceability to the vendor guaranteed for all products? Yes.

16.2.2 Is traceability to the manufacturer guaranteed for all products? No. In some cases we purchase materials from vendors which do not disclose the manufacturer's name.

16.2.3 Is the name of the manufacturer communicated to the customers for standard research products? This information is only disclosed upon request.

16.3 Quality Management Repacking, Re-labeling and Holding of Products

16.3.1 Does SAFC perform analytical testing on traded products to ensure that all lots meet the predefined specifications? Yes. All products are tested appropriately following written instructions.

16.3.2 Are results from supplier certificates accepted without testing? Yes, in predefined cases data is taken from supplier CofAs.

16.3.3 Is data copied from supplier CofAs marked as such in SAFC's CofA? No.

16.4 Repacking, Re-labeling and Holding of Products

16.4.1 Are traded products repackaged and relabeled by SAFC? Yes.

16.4.2 Is the packaging and labeling operation designed to prevent mix-ups and contamination? Yes. The packaging and labeling process for traded products is similar to the process for produced materials.

16.5 Stability

16.5.1 Does SAFC handle the traded materials according to the manufacturer instructions? Yes.

16.6 Transfer of Vendor Information

16.6.1 Is vendor information on imported products communicated to the customers? Yes, in cases like safety hazards, product mix-ups, this information is communicated to the customer.

16.6.2 Are sourcing changes communicated to customers? Yes, upon request change control and notification agreements can be set up.

16.7 Handling of Complaints and Recalls

16.7.1 Are complaints from customers communicated to the vendor/manufacturer in order to facilitate corrective actions at manufacturer side? Yes, as appropriate.

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