- Use of drinkable water, pure or mixed with non toxic / or food grade additives (e.g. thickening agent, color, salts, etc.) is mandatory
- Use of alcoholic compounds (e.g. glycol like substances, etc.) or petroleum paraffines are strictly prohibited. Because of their toxicity, they can be only used for internal purpose within tightly controlled closed loops.

5.2.2.1.2.2 Quality control

As elements of qualified process, they must be under quality control i.e.,:

- Written specifications
- Audited suppliers
- Checks at receipt if relevant, either on samples according to a sampling protocol or based on suppliers's quality certificates

Packaging specification must ensure that inner temperature values will not exceed authorized range during defined tranport and meet requirements set by temperature test profiles (e.g. steady or seasonal profile). Otherwise the material must be quarantined and the deviation reported.

5.2.2.1.2.3 Focus on freezing risk

Main risk is temperatures below specification (especially freezing risk) and for products to be kept at positive temperature, special attention must be paid to the following:

- Avoid any direct contact between product and cooling source (e.g. by using compartments, baffles or thermal buffers such as refrigerated water layers), particularly when dry ice is used for positive range of temperature (e.g. frozen carbon dioxide sublimates at -78,5° C (-109.3°F)).
- After receipt of product limit the cooling load and ensure all frozen gel packs are removed prior to being stored in refrigerated areas
- Temperature of frozen packs at the moment of use

5.2.2.1.2.4 Non refrigerated transport

On time delivery is required in order to meet customer requiments and ensure cold chain integrity

Time frame is essential because of limited self-sufficiency for passive cold chain shipments and must rely on:

- Real time tracking of the goods (e.g.: long distance tracking on the Internet or exception report)

ROXANA MONTEMILONE
DIRECTORA TÉCNICA
SANOFI PASTEUR S.A.

CHRISTIAN DOMINGUEZ
APODERADO
SANOFI PASTEUR S.A.

- Sanofi pasteur decision (e.g.: re-delivery, return, etc.) in case of delay, failure or any incident reported by the the provider

Service Agreement must pay specific attention to safety risk during breaks in transit.

5.2.2.2 Selection of the route and carriers

According to availability for desired area, selection must be based on following criteria (non exhaustive list):

- Local or international quality certification / acknowledgement (e.g. ISO 9000)
- Preference must be given to carriers that have cold chain services
- Other pharmaceutical customers and known quality SOPs dedicated to health products
- Subcontracting organization and level (2nd or 3rd part) at picking of goods, intermediate storage or cross-docking and final delivery steps (e.g. owned vehicles fleet vs. hired)
- Availability of a tracking system on real time
- Business reliability (e.g. rated insurance company, etc.)

Selected carriers must be audited initially during sourcing phase (quotation/bid => short list) and then periodically all long partnership (follow up).

Besides GMP guidelines, carriers audits must emphasize on, and not limited to:

- Internal SOPs and training
- Maintenance of vehicles
- Regular preventive maintenance and calibration of refrigeration units and monitoring devices
- Tracking reliability (position, temperature, incidents)
- Potential crossed flows with non pharmaceutical products when relevant
- TOR control and temperature deviations management
- Contingency plan

ROXANA MONTEMILONE
DIRECTORA TÉCNICA
SANOFI PASTEUR S.A.

CHRISTIAN DOMINGUEZ
APODERADO
SANOFI PASTEUR S.A.

5.3 Temperature monitoring

5.3.1 Monitoring principles

Appropriate tracking of temperature conditions must be designed and implemented when required to demonstrate at any time in the process of storage and distribution whether product has been exposed to a combination of excessive heat or cold over time and whether it is likely to have been damaged.

Monitoring tools can use a mix of available means to follow temperature: indicators, tracers, data loggers.

Making data-based decisions for product use requires high reliability of collected data using tested indicators or calibrated data loggers ensuring accuracy of measurement.

5.3.2 Tools

5.3.2.1 Indicators

Easy to use and immediately readable at receipt to make acceptance / quarantine decision they neither require any computer-software equipment to download data nor calibration for each item (characteristics only need to be certified by the manufacturer).

Models which require pre activation are strictly single use devices.

Because of chemical components, supplier's indicated shelf life must be respected.

As elements of quality decisions, they must be under quality control (i.e. written specifications, audited suppliers and checks at receipt by sampling when destructive tests or receipt of Certificates of Conformance).

Required temperature measurement accuracy is +/-1°C(1.8°F) or better when possible.

Indicators shall be used according to site requirements.

Note : VVM is an indicator which could substitute other models when it is present on product.

5.3.2.2 Tracers (tags)

Equally easy to use and immediately readable at receipt to make acceptance / quarantine decision, they do not require any computer-software equipment to download data but require supplier calibration for each item (electronic programs and chipset must be certified by the manufacturer).

All models require starting activation (instantaneous / or delayed starting) and are strictly single use devices.

ROXANA MONTEMILONE
DIRECTORA TÉCNICA
SANOFI PASTEUR S.A.

CHRISTIAN DOMINGUEZ
APODERADO
SANOFI PASTEUR S.A.

Because of batteries (not always removable when sealed), supplier's indicated shelf life must be respected.

As elements of pharmaceutical decisions, they must be under quality control (i.e. written specifications, audited suppliers and checks at receipt by sampling when destructive tests or receipt of Certificates of Conformance).

Required temperature measurement accuracy is +/-0,5°C (0.9°F) or better and other technical specifications (e.g. storage temperature range, operating temperature range, display visibility range, time measuring accuracy, initial delay, recording period, storage before START, data retention after STOP, sampling frequency, etc.) must be defined according to monitoring purpose.

Tracers must be used according to site requirements.

5.3.2.3 Data loggers (recorders)

They must be readable at receipt, requiring in some cases local computer-software equipment to download data (some devices offer an immediate display summarizing alarms and may need specific equipment to retrieve the whole record).

Measurement frequency (sampling intervals) must be consistent with desired autonomy which is limited by memory capacity (e.g. 1Ko = 1024 points divided into X hours) but in any case must not be less than a minimum of 1 measure per hour and ideally between 2 and 5 measures per hour.

As for tracers, required temperature measurement accuracy is +/-0,5°C(0.9°F) or better and other technical specifications must be defined according to monitoring purpose.

As elements of quality decisions, they must be under quality control (i.e. written specifications, audited suppliers and checks at receipt by sampling when destructive tests).

Multiple-use models require sanofi pasteur calibration and maintenance (e.g. batteries removal) for each item (internal or subcontracted to specialized metrological agreed laboratory).

Single-use models require supplier calibration for each item (electronic programs and chipset must be certified by the manufacturer).

Data loggers must be used to monitor temperature of inter company shipments and may be used for international and domestic shipments if the customer requires detailed temperature data.

5.3.3 Data management

For all inter company shipment and when required by customers, Temperature data must be read at delivery point so that consignee must be able to analyze them and shipper has to make decision (e.g. release the product / or keep it under quarantine status / or accept it under restrictive condition / or reject it) except under specific mutual agreements.

Shipping site must be informed of monitoring results by exception, and in case of complaints or when temperature deviations are recorded vs. defined shipping specifications, it enters deviations in its own quality management system.

Single use temperature monitoring devices must not be returned except on special shipping site's request (e.g. investigation purpose).

Multiple use temperature must be either returned or re used within a closed loop after having saved / or backed up their recorded data (devices might get lost or data erased during return trip, which could lead consequently to potential discard decision for concerned products).

Shipping site is responsible for managing investigation about temperature deviations recorded during transit time, while receiver is responsible for eventual temperature deviations recorded after receipt.

5.4 Validation & Qualification

5.4.1 Preliminary statement

Validation is documented testing, performed under controlled conditions, which demonstrate with a high degree of assurance that a specific a process consistently produces a result meeting pre-determined acceptance criteria.

Validation process fully applies to storage but transport may only be qualified.

Although process robustness is designed through "worst case" conditions to overcome all foreseen random variations, it is not possible to actually control, all the parameters that could affect the transportation process (e.g. weather, customs, traffic delays, mechanical failures, duration of transport, etc.).

By studying these variables in multiple combinations, an organization is able to gain a level of confidence regarding how their packaging, processes and actions of their contracted service providers will work together with the common goal of safeguarding a product during storage and distribution. While quality principles are used to reliably qualify the cold chain distribution process, it is to be acknowledged that even a qualified process is subject to change over time. Therefore, periodic and appropriate monitoring is recommended. The frequency and type of monitoring will be based on the specific conditions of a given distribution process.

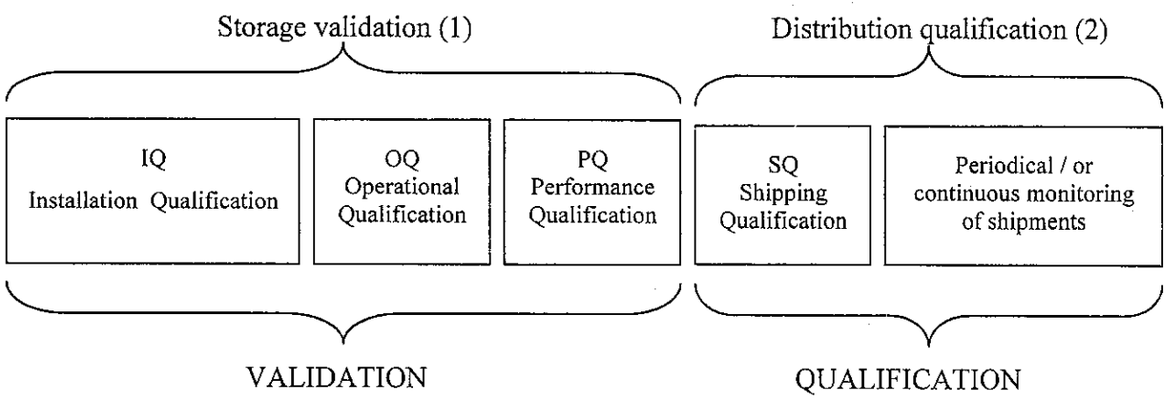
One other important thing to be aware of is that not all trailers are the same, even if they are the same manufacturing model and they will not perform similar over time (it has been shown that the insulation degrades and lead to different results from trailer to trailer).

Hence, transportation processes can be qualified rather than validated and require further monitoring after initial tests (continuous or predefined periodic tests). Full validation of transport is impractical considering the infinite number of authorized means / or routes and potential combinations of commercial carriers and flight schedules (even captured in procedures or service agreements). Provider can only be approved but not qualified.

ROXANA MONTEMILONE
DIRECTORA TÉCNICA
SANOFI PASTEUR S.A.

CHRISTIAN DOMINGUEZ
APODERADO
SANOFI PASTEUR S.A.

Differences between validation and qualification can be shown by the following scheme:



(1) Storage processes of pharmaceutical production are performed in a "highly – controlled" environment. Therefore, it can be validated.

(2) The distribution process does not operate under "highly – controlled" environment. Therefore, it cannot be validated but only qualified and then monitored.

5.4.2 Objectives

The aim is to demonstrate that products are stored as per product label and distributed according to specific conditions that have been established and officially approved (in any case, stability data must support the methodology).

Validation can be prospective, concurrent or retrospective.

5.4.3 Principles and Methods

Processes are assessed through IQ, OQ and PQ/SQ.

Based on IQ, OQ and PQ results for the storage it leads to a validation, ensuring product are properly stored.

Based on OQ and SQ results for the transport it leads to a qualification reflecting the capability and the robustness of processes.

5.4.4 Validation of refrigerating facilities (IQ, OQ, PQ)

Range of temperatures and capacity may vary according to stored products:

- < 25°C (77°F) = HVAC (Heating, Ventilation and Air Conditioning)
- 2°C (35.6°F) to 8°C (46.4°F) = cold excluding freezing
- <-20°C (-4°F) or below (freeze) excluding thawing

Acceptance criteria must fit with storage temperatures given on product labels to ensure optimum quality of the products throughout their shelf-life.

Tolerances that may be considered during a very short time for interlocking areas (e.g. (un)loading bays in warehouses where transient rises in temperature may occur when doors are opened) must be supported by stability data and related to controlled TOR management procedure.

5.4.4.1 OQ for cold / or freeze rooms

A tri dimensional temperature mapping test has to be performed to localize "worst case" areas, showing «hot» points (e.g. next to the doors, near the ceiling if evaporator airflow cannot reach certain areas generating hot air "pocket") and « cold » points (e.g. at the opposite of doors, under direct exposure or close proximity to cooling coils, under cold air streams, on floor contact if ground is poorly insulated, etc.).

In geographical areas where climate is not temperate (extremes of external temperature can be met), the "worst case" exercise must be performed both during summer and winter seasons to achieve the OQ.

For the same reasons, temperature mapping must be repeated after significant modification to the premises or changes in stock layout.

Then temperature loggers must be placed at the closest of the products, both at worst case points and average positions reflecting homogeneous temperature, for PQ and routine continuous monitoring (every cold store must have at least 2 temperature sensors).

Mapping must take into consideration partial and fully loaded scenarios (repeat trials to ensure consistency).

Monitoring devices must be independent of controlling probes and must be calibrated regularly regarding an internal / or an official standard (e.g. a minimum of a three-point calibration carried out on an annual basis) and routinely maintained.

Every cold room / or store and freezer room must be equipped with an automatic recording device capable of continuous or intermittent temperature monitoring and fitted with 24/24 hours alarm contacts.

ROXANA MONTEMILONE DIRECTORA TÉCNICA SANOFI PASTEUR S.A.

CHRISTIAN DOMINGUEZ APODERADO SANOFI PASTEUR S.A.

Pen recorders recording continuously (paper chart on disc / or drum) and digital recorders are suitable as long as the whole measurement chain has been calibrated, nevertheless centralized report to electronic center (PC / or server / or Programmable Logic Controller) is recommended for multi channels systems.

Dial / or stem thermometers can be used for instantaneous temperature reading but not for monitoring purpose.

The procedures for checking functionality and compliance of the unit with its temperature specifications (e.g. daily checks for monitoring systems and alarms accordingly) must be in place.

Temperatures must be recorded in continuous and checked periodically by a responsible member of staff.

Simplified temperature homogeneity tests must be performed periodically (e.g. on annual basis) to confirm in time OQ reliability.

Regarding the storage volume, suitable alert limits must be set for temperature alarms in order to prevent risk of deviation before going beyond the upper / or lower specification action limit.

The power back-up facilities for the unit itself and for the temperature must be in place and periodically tested.

A contingency plan describing corrective actions to be taken to safeguard the vaccine must be established in case of long power cut or refrigeration equipment failure (e.g. auxiliary fuel power generator, door closure, spare part stock and full service maintenance contract, stock transfer to other location, etc.).

5.4.4.2 Specificities for low volumes storages (fridge / or freezer)

A simplified temperature mapping test must be performed during OQ to localize "worst case", showing «hot» points (e.g. on the top, next to the door for top opening models, at the bottom and in all zones directly exposed to ambient temperature when door open, for front opening models) and « cold » points (e.g. at the bottom for top opening models, especially if ice-lined, near the freezing compartment for front opening models).

Regarding the low internal volume, load variations are likely to have considerable impact and must be taken into account.

Temperatures must be recorded:

- Either in continuous
- Or through a max-min thermometer which must be placed at appropriate position identified during temperature mapping studies and checked at least daily by a responsible member of staff

5.4.5 Qualification of containers (OQ)

It consists of consecutive replicate field transportation tests to demonstrate that the process is effective and reproducible regarding packaging and insulating functions (when relevant for isothermal containers).

As much as possible, this process capability assessment must be performed before launching tests in real situation.

If preliminary trials demonstrate that results are most of time within specifications range, with a low random variation impact, thus the solution can be qualified.

Otherwise, a poorly capable process showing high random variation impact must be improved before validation, by running static trials (e.g. using standard temperature profiles).

Testing must be performed using typical load configurations.

Sound rationale to justify the number of tests and load configurations (as applicable) must be stated in the protocol that includes:

- Actual ambient temperature variances, including seasonal changes, customary in transportation
- Representative transportation load configurations
- Defined packing configuration(s)

5.4.6 Qualification of shipment (SQ)

Qualification is an important quality tool which allows to demonstrate the performance of a shipping process. However, it has to be completed by other quality insurance concepts to control the process (audits, performance follow-up, etc.).

It can be divided into 2 steps:

- SQ1 must only take place after having assessed process robustness and consist of first run with sufficient number of tests (minimum = 3) to check repeatability.
- SQ2 must follow the SQ1 and include periodically performed retests and / or continuous monitoring to highlight significant variations. Concurrent and retrospective qualification must be recorded and assessed.

5.4.6.1 Refrigerated vehicles / or containers

Capability is usually good and worst case definition must focus on temperature mapping inside the truck / container.

5.4.6.1.1 SQ1

A tri dimensional temperature mapping test has to be performed to localize «hot» points (e.g. next to the doors, near the ceiling if evaporator airflow cannot reach certain areas because of the full load) and « cold » points (e.g. at the opposite of doors, on contact with floor and walls, under direct exposure of cold air streams under cooling unit, etc.).

Qualification strategy must be representative. If the qualification of all the vehicles of a road carrier cannot be performed, the applied strategy must be justified (refrigerated vehicle typology, vehicle generation, percentage of vehicles tested, etc.).

If the load is not standard (volumetric evaluation + thermal inertia linked to weight and water percentage), the strategy must be justified. In a theoretical point of view, full load can be considered as a worse case (maximum barrier effect to the internal air convection).

Then temperature loggers must be placed at the closest of the products, both at worst case points and average positions reflecting homogeneous temperature (every TL must have at least 1 temperature logger and more if temperature homogeneity within specification, cannot be obtained).

Main risk is temperatures below specification (especially freezing risk) and for products to be kept at positive temperature, special attention must be paid to the following:

- Avoid any direct contact between product and cold air flow.
- Set strict SOPs with shippers (freight forwarders and air companies) to store refrigerated containers above 15°C (59°F), meaning no cold room during all ground handling operations and to limit transit time on tarmac area during winter.

5.4.6.1.2 SQ2

It is based on a continuous monitoring for each shipment with at least 1 duly qualified logger independent of truck (container) controlling / or monitoring probes:

- If truck / or refrigerated container is monitored with a logger (available record), then 1 logger is suitable
- If truck / or refrigerated container is not monitored with a logger (instantaneous display only), then 2 loggers are required

Probe position must be relevant to reflect the most accurately temperatures variations inside the products.

Tolerances that may be considered during a very short time if (un)loading operations happen in non refrigerated areas / or bays, must be supported by stability data and related to controlled TOR management procedure.

Cold chain breaks occurring during the transit time (whatever the root cause) must be treated through the quality deviation management system, refer to the CQR/Failure Investigations Management, GQ_000506 (see the Appendix 1).

ROXANA MONTEMILONE
DIRECTORA TÉCNICA
SANOFI PASTEUR S.A

CHRISTIAN DOMINGUEZ
APODERADO
SANOFI PASTEUR S.A

5.4.6.2 Insulated containers

Capability is usually poor according to a wide range of destinations and variable climatic conditions to be met, therefore worst case definition must focus on seasons, route parameters and packaging configurations.

5.4.6.2.1 SQ1

A climatic assessment based either on meteorological data collection or preliminary trials or experience, has to be performed during SQ1 to localize «hot» destinations (e.g. tropical countries) and «cold» destinations (e.g. continental winter).

Time frame assessment will give the "risky" routes (e.g. stops and go, long distances from shipping point, etc.).

If the load / or the packaging is not standard (e.g. temperature, product type, etc.) trials must be repeated for each significantly different configuration.

The potential high number of tests to launch (e.g. climatic destinations * route parameters * packaging configurations * 3 trials for repeatability) can be reduced by crossing parameters (e.g. experiment matrix methodology).

Then temperature loggers must be placed at the closest of the products + at external position:

- The minimum number of internal probes depends on the reference to be used (cf. WHO) and may vary within a range of 2 (minimum to reflect potential lack of homogeneity) to 9 (8 corners + tri dimensional middle position) and above.
- Probes must be inserted at most relevant positions regarding risk analysis (e.g. faces of the boxes exposed to sunlight or in direct contact with cold surface, etc.).

An exception to this may be made for one time research or development shipments as long as they are further monitored by loggers with assessed insulated containers (i.e. continuous monitoring replaces trials in real conditions).

ROXANA MONTEMILONE
DIRECTORA TÉCNICA
SANOFI PASTEUR S.A.

CHRISTIAN DOMINGUEZ
APODERADO
SANOFI PASTEUR S.A.

5.4.6.2.2 SQ2

It can consist **either of periodic retests** performed according to SQ1 conditions **or continuous monitoring** performed and assessed with predetermined means regarding identified flows.

Chart below features **minimum requirements** which can be improved according to local SOPs / or customers' requirements (reinforced monitoring secures the data reliability and may help to make pharmaceutical decisions). Other local requirements may be requested by customers (e. g., shock evidence devices).

Note: as well as for SQ1, logger's probe as well as indicators position must be relevant inside the box to reflect the most accurately temperatures variations inside the products.

Flow of goods / Required temperature monitoring device	Inter company shipment		Other shipments (including sales)		Clinical Trial Materials	
Indicator	NA	NA	1 per box IF SQ2 has not been performed (NOT mandatory otherwise)	Device can be selected to reflect the major identified risk (e.g. freezing / or overheating)	NA	NA
Tracer (tag)	1 per box or better	Device can be selected to reflect the major identified risk (e.g. freezing / or overheating)	-	Can be used in substitution of indicator	NA	NA
Logger	2 per "delivery batch"	Loggers must be duly qualified and "delivery batch" is defined on basis of order size (same consignee) / or AWB size (all boxes loaded in same aircraft). If all the boxes are not monitored, deviations recorded by the logger will apply to the whole "delivery batch".	-	Can be used in substitution of indicator	1 per box	When delivery point is out of routine closed loop, the device should preferably feature immediate display for alarms (e.g. LCD; flashing LED, etc.)

Tolerances that may be considered during a very short time and are part of indicators selection (e.g. freezing evidence devices reflect temperatures from 0°C (32°F) and below but not between 0°C (32°F) and +2°C (35.6°F)), must be supported by stability data and related to controlled TOR management procedure.

Cold chain breaks occurring during the transit time (whatever the root cause) must be treated through the quality deviation management system, refer to the CQR Failure Investigations Management, GQ_000506.

5.5 Returns management, including recalls

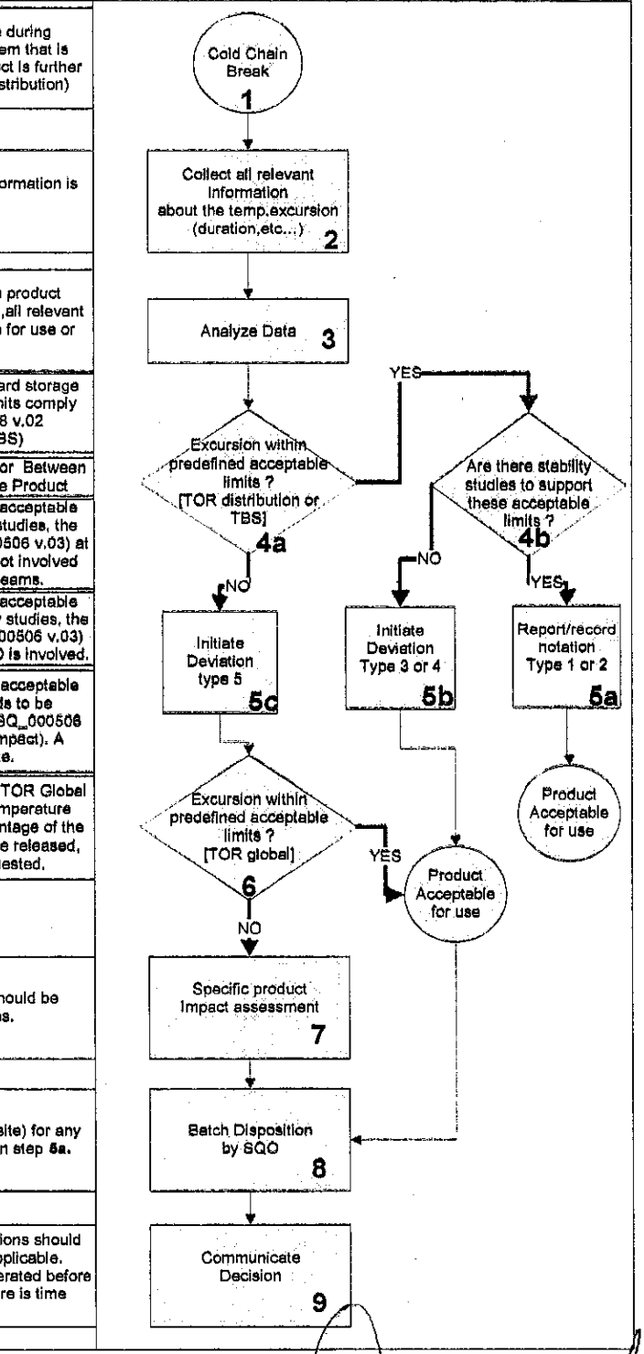
Only product remaining property of the company (e.g. from sanofi pasteur sites, affiliates or clinical trials investigators, etc.) shall be considered:

- Criteria for accepting returns must be established and there must be mechanisms in place for ensuring that storage conditions are maintained when the product is outside the shipping site.
- Returned products have to be examined and assessed by an authorized person. This assessment must take into account the nature of the product, any special storage conditions it requires, and the time elapsed since it was issued. Special attention must be given to products requiring special storage conditions. As necessary, advice must be sought from the holder of the marketing authorization or the Qualified Person of the manufacturer of the product. Records of returns must be kept. The responsible person must formally release goods to be returned to stock. Products returned to saleable stock must be placed such that the "first expired first out" system operates effectively.
- Non-defective finished products, which have been returned must be kept apart from saleable stock to prevent redistribution until a decision has been reached regarding their disposal (taking into account quality criteria and suficient remaining shelf life period).
- If there is a possibility that the cold chain has been compromised because the entire process is not qualified (i.e. delivery, receipt, local storage, repackaging, and collection) or no temperature monitoring system was attached, the returned products will be destroyed.
- Product complaints must be recorded and forwarded to the manufacturing site, following the appropriate complaint procedure, refer to the CQR Management of Technical Complaints, GQ_000868.
- Recalled and counterfeit returned products must be managed according to respective specific SOPs.
- The destruction of products must be carried out in compliance with the pharmaceutical regulations and HSE requirements and records must be kept.

ROXANA MONTEMILONE DIRECTORA TÉCNICA SANOFI PASTEUR S.A.
CHRISTIAN DOMINGUEZ APODERADO SANOFI PASTEUR S.A

Appendix 1: Cold Chain Break Deviation Management

	REQUIREMENTS and COMMENTS
1	All shipments that need a refrigerated temperature during transportation contain a temperature measuring system that is checked upon arrival at the delivery point before product is further processed for use (GQ_000863 v.01/Storage and Distribution)
2	When a temperature excursion occurs,all relevant Information is centralized for further analysis.
3	There is a system in place that ensures that when a product suffered a temperature excursion during transportation,all relevant data are analyzed to state if the product is acceptable for use or needs further investigation.
4a	There are predefined acceptable limits (beyond standard storage temperature range) described in a site SOP.These limits comply with the requirements or principles of GQ_000848 v.02 for TOR distribution or TOR Between Sites (TBS)
4b	The limits that have been defined for TOR Distribution or Between sites are supported by stability studies specific to the Product
5a	When the temperature excursion is within predefined acceptable limits for TOR Distribution and supported by stability studies, the incident is recorded as a Notation type 1 or 2 (GQ_000506 v.03) at the shipping site.There is no product impact.SQO is not involved but the system is periodically audited by Quality teams.
5b	When the temperature excursion is within predefined acceptable limits for TOR Distribution but not supported by stability studies, the incident is recorded as a Deviation type 3 or 4 (GQ_000506 v.03) at the shipping site.There is no product impact but SQO is involved.
5c	When the temperature excursion is above predefined acceptable limits, there is a potential product impact that needs to be evaluated.This requires a formal investigation as per GQ_000506 v.03 (recurrence analysis, root cause and product impact). A deviation type 5 is initiated at the shipping site.
6	The investigation should include the calculation of the TOR Global (as per GQ_000848) and state whether or not the temperature excursion is within predefined acceptable limits (percentage of the TOR global).If the answer is YES, the product could be released, no further investigation for product impact is requested.
7	If the answer is NO, the potential product impact should be evaluated via specific analysis and /or studies.
8	Batch disposition should be made by SQO (shipping site) for any temperature excursion excepted those mentionned in step **5a.**
9	The decision on the Batch and potential other instructions should be communicated internally and externally when applicable. Note :communication of product disposition may be tolerated before completion of the root cause investigation when there is time sensitivity.



ROXANA MONTEMILONE
DIRECTORA TECNICA
SANOFI PASTEUR S.A

CHRISTIAN DUMI
APODERADO
SANOFI PASTEUR S.A

3.2.P.3.5

Validación y/o Evaluación del Proceso

ROXANA MONTEMILONE
DIRECTORA TÉCNICA
SANOFI PASTEUR S.A.

CHRISTIAN DOMINGUEZ
APODERADO
SANOFI PASTEUR S.A

Sección 3.2.P.3.5 - Validación y/o evaluación del proceso

Índice

ROXANA MONTEMILONE
DIRECTORA TÉCNICA
SANOFI PASTEUR S.A.

CHRISTIAN DOMINGUEZ
APODERADO
SANOFI PASTEUR S.A.

Lista de tablas

ROXANA MONTEMILONE
DIRECTORA TÉCNICA
SANOFI PASTEUR S.A.

CHRISTIAN DOMINGUEZ
APODERADO
SANOFI PASTEUR S.A.

ROXANA MONTEMILONE
DIRECTORA TÉCNICA
SANOFI PASTEUR S.A.

CHRISTIAN DOMINGUEZ
APODERADO
SANOFI PASTEUR S.A.

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