Outline of a quality system and standard for the certification of conformity

Although still in early steps, novel Additive Manufacturing (AM) processes are growing in expectations as enabling technology for manufacturing metal parts with higher added value. They provide many advantages in comparison with conventional processes. Some of the potential applications very hopeful, and therefore, considered in ManSYS, are those for manufacturing aircraft components and medical devices due to a higher potential payoff versus conventional manufacturing processes such as forging, casting or machining. But those markets are characterised by a legal framework for operating properly into them. Every part in those markets has to be certified according to the regulations established by the corresponding authorities. As AM is a novel technology, new certification concepts have to be defined which are required by the specific characteristics of the technology and the lack of experience.

Before certifying a part, it is required to qualify the manufacturing process that includes the use of technology as well as material processed by it.

What does qualify a manufacturing process?

Process qualification is the qualification of manufacturing and production processes to confirm they are able to operate at a certain standard during sustained commercial manufacturing. It should be noted that equally important as qualifying processes, equipment and material is qualifying the material, software and personnel. Once all processes have been qualified the manufacturer should have a complete understanding of the process design and have a framework in place to routinely monitor operations. Only after process qualification has been completed can the manufacturing process begin production for commercial use.

For the certification of AM parts a new Process Qualification Procedure is necessary taking into account the critical parameter of AM as well as the material supply and the technology's capability.

In ManSYS, process qualification procedures and registers are defined and a manual is implemented that specifies a method by which the components processed as it has been specified are examined to ascertain if they meet the required specifications (qualifying criteria) in a repeatedly manner to be identified as qualified.

It has been considered two novel standards for developing a process qualification method for additively manufactured components using full-melt powder bed fusion such as electron beam melting and laser melting: ASTM F2924 standard specification for Ti6Al4V and F3001 for Ti6Al4V ELI (Extra Low Interstitial).

The method developed will provide information for knowing about the variables and factors that may influence in the AM process and its relations with other post-processes. This knowledge will serve for specifying the correct operation window for process planning, and for establishing methods for component qualifying.

A qualification approach for AM

The development of the qualification method shall include the following items:

- The component requirements specifications
- Manufacturing plans
- Feedstock
- Bulk material
- Component manufactured

This document describes the issues to be considered regarding the abovementioned items, presents the ManSYS case studies and introduces the developed quality management system for AM.

Component requirements specifications

The requirements specification will drive the qualification method, herewith even, the component design, and the manufacturing plan. Once the design of the part and the manufacturing plan are implemented, verification of the component will be carried out against the requirements specified.

Manufacturing plan

Once the component requirements have been specified a manufacturing plan for qualification can be specified. Qualification procedures require the assessment of several build cycles in which chemical composition specimens, from powder lots and bulk material as well, are prepared and measured. If the component requirements specified consider additional behaviour properties, the corresponding coupons shall be prepared.

Location, orientation on the build platform, number of test specimens for each machine qualification build cycle, and relationship between specimen test results and component quality shall be established.

Prior to proceed with the process qualification, it is convenient to ensure issues related with the control of the AM plant. These issues shall include, but is not limited to have the machine and the corresponding peripheral installed, maintained and calibrated as it is specified by the machine supplier; to use the software version and the set of parameters according to the material to be processed as it is specified by the machine supplier; and to have the machine operators approved and updated as it specified at least by the machine supplier and/or it is required for the process qualification.

Feedstock

As part of the manufacturing plan for qualification it is included the specification of the feedstock. The feedstock shall be metal powder. Special attention will be required to the impurities in material chemistry and high chamber temperatures.

There are some causes, which may affect to the presence of inclusions and impurities in the chemical composition of the powder, even in the as built material, such that the final material chemistry will be not in accordance with those specified in the corresponding material standard. The use of non-dedicated machines for one specific metal, which requires changing the powder alloy periodically; it is one of the most relevant cause of the powder contamination.

High chamber temperature –case of EBM- during building derives in a variation in chemical composition regarding virgin powder due to evaporation of some elements. During handling, some alloys may suffer significant oxygen pick-up, even due to humidity inside the build chamber, which may not be completely eliminated. Oxygen pick-up, may increase material fragility, but also affects powder fluidity, avoiding proper powder distribution in layers and may produce bad fusion between them.

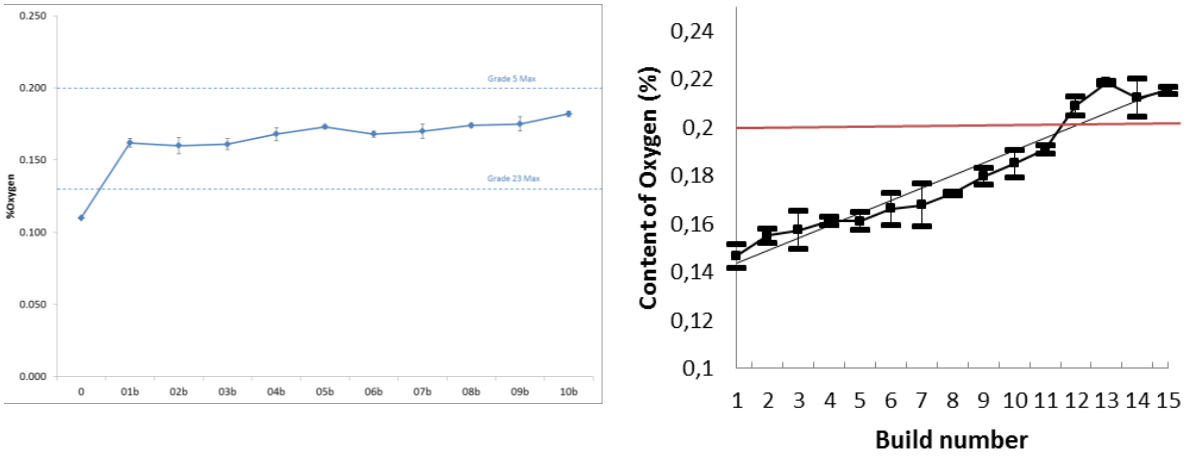

Figure 1: Evolution of the oxygen content when the powder is reused several build batches. Oxygen results x-axis shows the sequential build number. The chart above shows the test result for SLM, down for EBM.

The use of the used powder is allowed, but additionally to the effects of variance in the chemical composition described above, modifications in other powder properties such as size distribution, particle shape, tap density and flow rate may produce also bad fusion.

Powder blends are allowed unless otherwise specified between the component supplier and the component purchaser, as long as all powder used to create the powder blend meet the requirements listed in the corresponding standards and lot numbers are documented maintained.

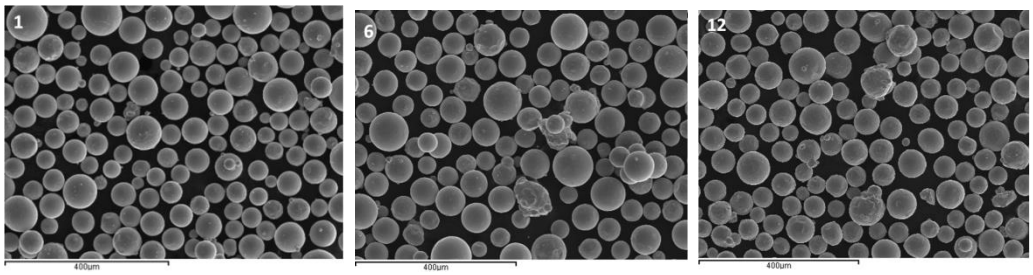

Figure 2: EBM Powder morphology after 1, 6 and 12 builds

Therefore, it is convenient to consider in the process qualification the assessment of the amount of inclusions and impurities present in the chemical composition of the feedstock; and the assessment of the feedstock properties variation along several build cycles. This study allows gathering important information about the feedstock such as, the identification of the critical element in the chemical composition; and a correlation of the percentages by weight of the critical element between the as built material and powder. This information shall drive the procedure for blending the powder and shall provide the maximum number of times used powder can be used as well as the number of any portion of a powder lot can be processed in the build chamber.

Bulk material

As part of the manufacturing plan for qualification it is included the specification of the post-processing sequence of operations. Post-processing operations may be used to achieve the desired shape, size, surface finish, or other component properties.

According to the component requirements specified, a structural performance of the bulk material shall be characterised in the process qualification method.

Therefore, once the feedstock studies described in the prior section have been conducted, the critical element has been identified and the powder blending has been specified, the bulk material shall be characterised. That means, the structural properties of the bulk material shall be predictable.

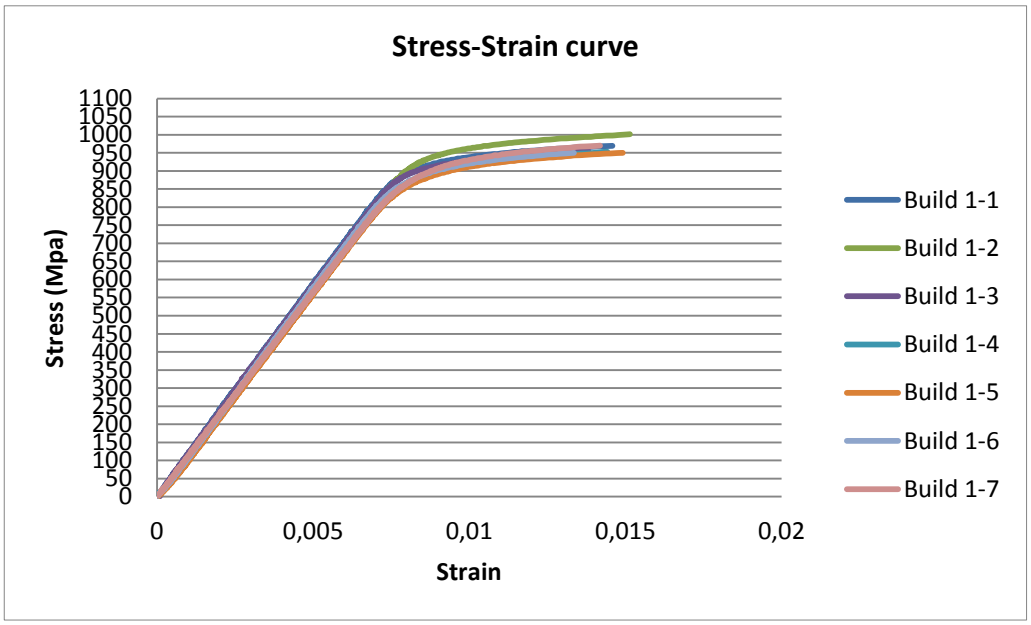

Figure 3: Mechanical tests results for tensile specimens processed by EBM

Component manufactured

The component properties depend on the position and location of they are processed on the build platform. The design of the support structures may influence in the result of the component processed by additive manufacturing. Support structures act as not only for supporting the weight of the material when it is melted if not also as heat conductor between the melt point and the build platform. Distortion during and after this process is mainly due to thermal gradients and local strains caused by phase changes. It cannot be avoided, but the support structure can be designed in such a way that distortion is minimised. Post-processing operations may be used to achieve the desired shape, size, surface finish, or other component properties.

On that case, it is required finally an assessment of the component properties in order to qualify if the process for manufacturing the component as it is specified in the manufacturing plan shall comply the component requirement specifications.

ManSYS case studies

Different case studies are considered in ManSYS for researching about the AM implementation in the manufacturing process of a metal part.

- For dental market, it is considered a prosthetic implant abutment from the company Twocare and a dental bridge for dental restoration from the company Wisildent.
- For medical device market, it is considered a intramedullary nail from the company Smith & Nephew's.
- For aircraft market, it is considered a bracket from the company GE Aviation.

For all these demonstrator parts, a component requirement specification has been conducted. In this specification it has been described the specification of the product, from both a technical and business perspective; a product description; a list of applicable standards; the failure modes and the test for component qualification.

A survey to the end users has been used for ascertaining the relevant quality aspects of future products which must be ensured by the ManSYS platform. The quality issues are expressed in terms of material properties of processed and/or final product after it has gone through the supply chain. Material properties are divided into four categories:

- *Form*: this category defines the physical appearance of the product and is commonly used for defining conceptual models. It refers to feel, colour aesthetic features or surface finish;
- *Fit*: this category defines the properties relevant for the ability of the part to physically interface or interconnect with or become an integral part of another item or assembly. It includes all the properties from "Form" category;
- *Function*: defines the action(s) that an item is designed to perform. It is commonly used to define functional models; it includes all the properties from the "Form" and "Fit" categories;
- *Direct production part: this category includes all the properties from "Form", "Fit" and "Function" categories.*

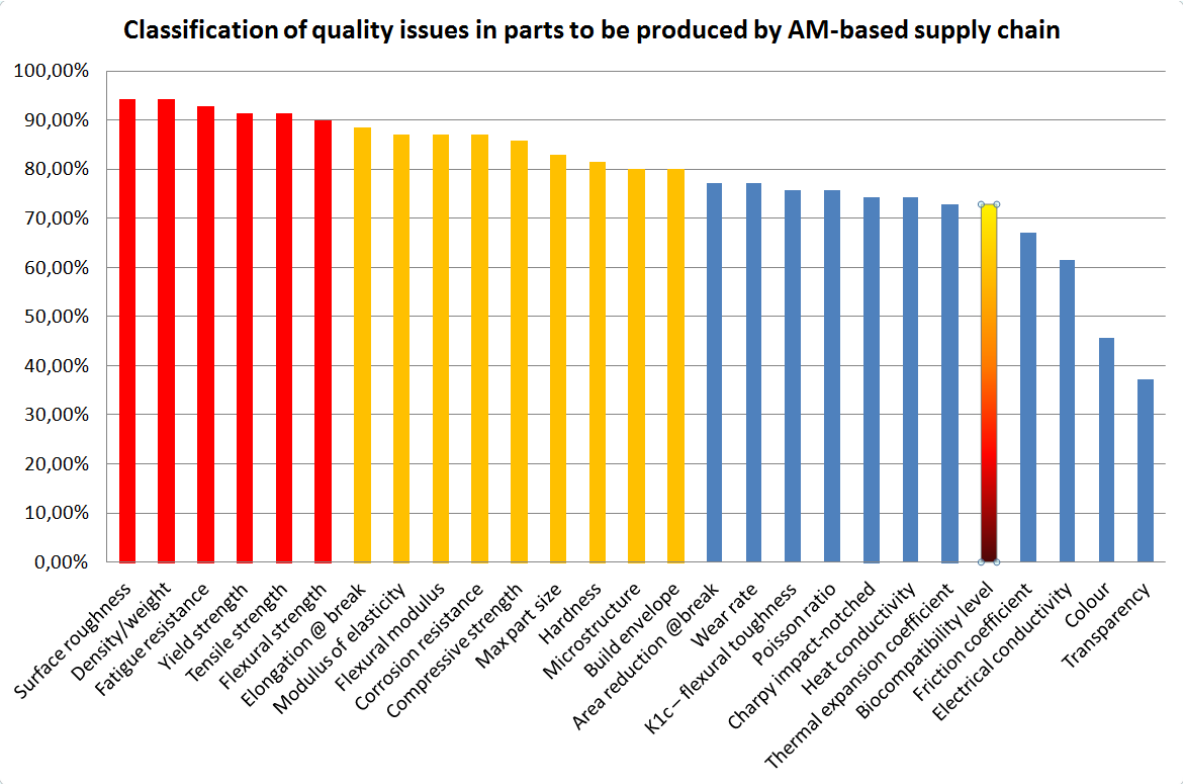

Figure 4: Classification of quality issues from survey in graphical form

Design rules, process and material database

Manufacturability of critical features is depending on several factors. Issues as minimum wall thickness, minimum horizontal diameter, maximum horizontal diameter, minimum vertical diameter, down-facing surface angle, maximum overhang, maximum bridge, thread and over-mass to be machined are geometric features dependant on the AM technology and the material to be processed.

A description of the process parameters settings for both technologies –SLM and EBM- has been specified and as built material characterisation has been documented for a standard set of process parameters.

All this information has been classified and stored for developing an AM knowledge database. The AM knowledge database provides information to the end users for applying in the process specification for the component such as quality, material and process conformance and data control within the supply chain.

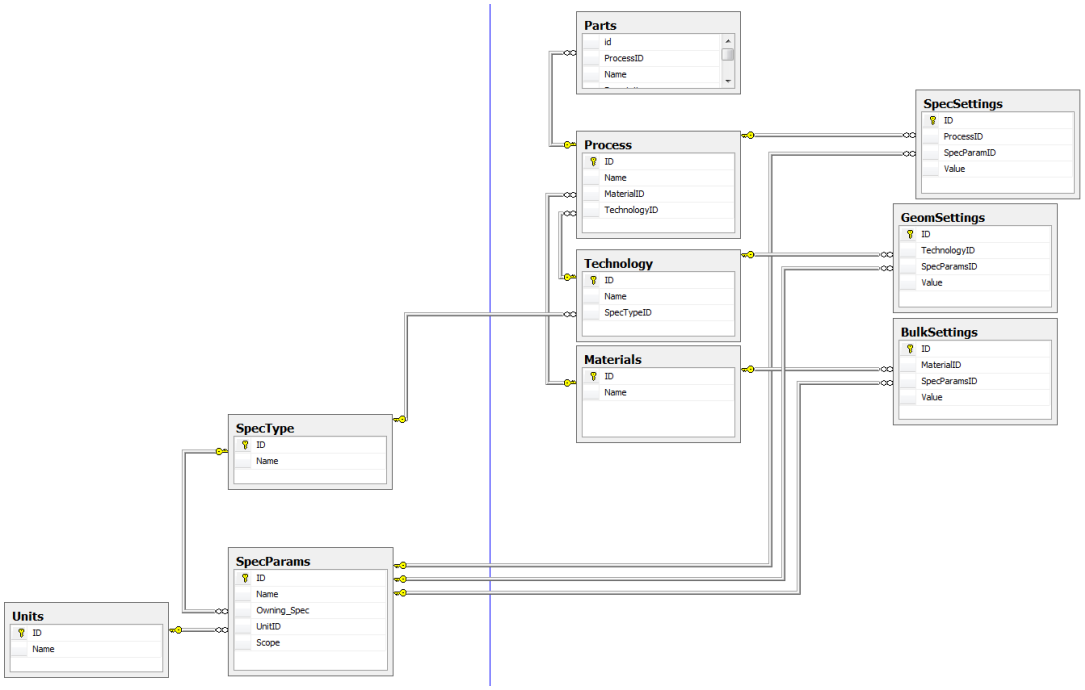

Figure 5: AM knowledge database structure

Some of the typical questions answered by the AM knowledge database could be:

If we specified a process for producing a component by EBM using Ti6Al4V, what are the bulk materal characteristics I can expect?, or, what are the geometric capabilities of such a process?, and, what are the corresponding setup parameters to be entered at the machine or during the CAM processing?

A Quality Management System for AM

To support the certification, any aerospace and medical device organization is prompted to control and calibrate all tools and equipment regularly so that the accuracy can be ensured. It further has to be guaranteed that the material meets the requirements and can be assigned to a batch and identified individually.

In ManSYS, a quality manual has been developed for the process as it is specified and qualified. Data covering critical process parameters must be recorded and analyzed to ensure critical quality attributes can be guaranteed throughout production.

In order to establish the basis of a Quality Management System (QMS) for a company which uses AM for designing and producing metal parts, all the relevant standards have been analysed. In particular, ISO 9000, EN 9110 and EN 9120 standards are considered for the aerospace industry; and ISO 13485 standard for medical devices. The referred ASTM F2924 and F3001 are considered in the QMS as well.

General procedures, operational instructions and control procedures have been developed to be included in a QMS. All information regarding Quality and Qualification aspects are stored in registers and the process traceability is guaranteed. Inherent of this QMS is the assessment and control of key feedstock and process parameters; the development of a fixed practice for each AM component; the verification of each fixed practice via NDI and destructive testing; and part-specific acceptance testing (both NDI and destructive testing) to ensure the integrity of part and its compliance with the requirements specified.

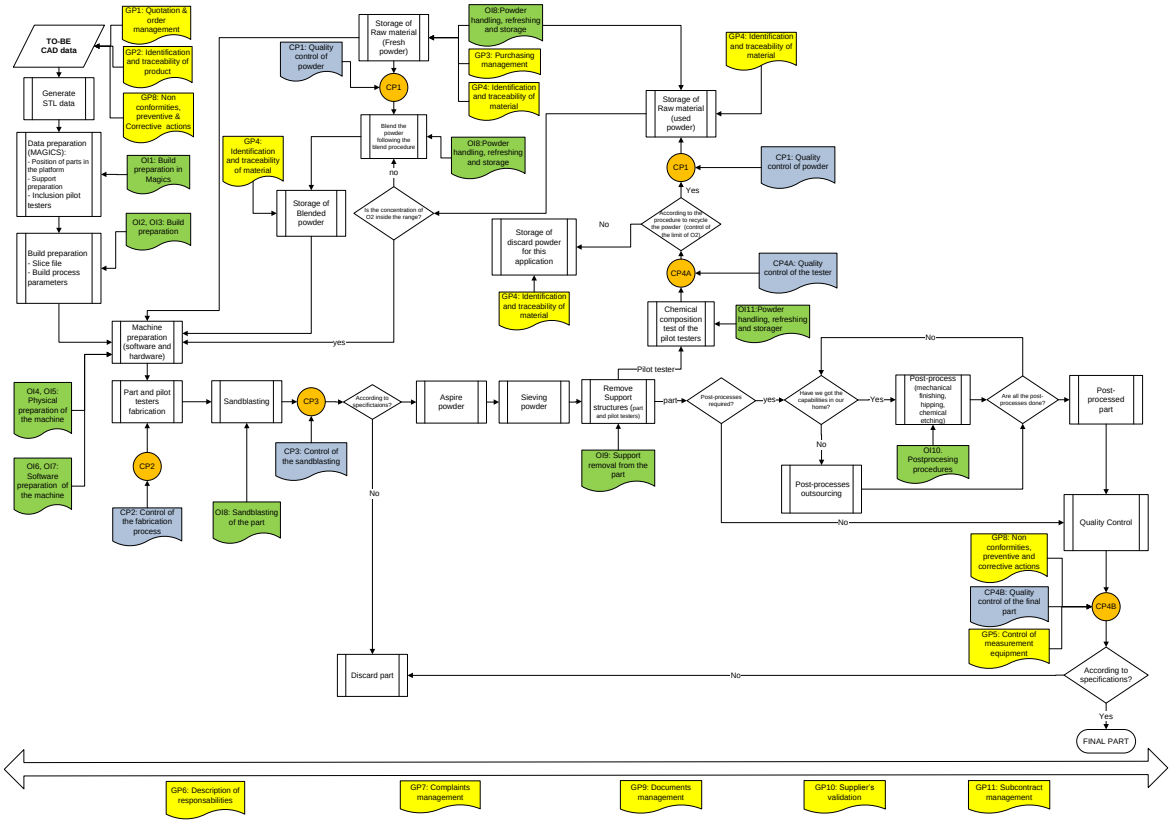

Figure 6: AM process flowchart

It is convenient to gather information during the melting process for assessing the process quality in real time. Issues such as oxygen content, energy and powder distribution, and dimensional accuracy should be monitored. In ManSYS, a state of art of the inspection monitoring systems has been done for implementing in the quality control.

Finally the QMS has been applied to the ManSYS demonstrators for validating all the developments. After the validation, the QMS should be integrated in ManSYS platform for producing metal parts with the level of quality required by the costumers.

How to guarantee Quality in ManSYS?

With the aim that services offered through ManSYS guarantee such quality level according to the end users requirement specifications, it is necessary for the service bureaus comply with a number of prerequisites.

The following prerequisites are those linked to Quality:

- *Quality Management System:*

  The Service Bureau shall be ISO certified within the specific markets. The part supplier and its metal powder supplier shall maintain a quality program recognized by the end costumer markets, such as ISO 9001, ISO 9100 or ISO 13485.

  The quality certificate of the Service Bureau shall include the scope of activities according to the role to be played in ManSYS, such as AM metal part production for operational excellent service bureau; AM metal part design for customer intimate service bureau; and AM metal part design and production for thought/product leader service bureau. In case of metal part production, it must be specified the type of AM machine(s) and material(s) considered in the scope of the quality certificate. This requirement must be met before registering to the ManSYS platform.

- *Quality Assurance:*

  The part supplier shall use and maintain a comprehensive manufacturing control system. It is allowed to have internal control measurements, but if it the parameter to be measured is critical for assuring the expected quality level, ISO 17025 certified laboratories should be considered for those cases. Additional coupons per batch shall be produced for component validation.

- *Part Inspection:*

  If it is specified by the end user, the part supplier shall use NDT and dimensional tests for assessing if the part meets the specifications. A certificate, including a complete test report, shall be provided by the component supplier at the time of shipment stating that the components were manufactured and tested in accordance with this specification.

- *Documentation Traceability:*

  All the documentation related to previous items shall be maintained and uploaded to the ManSYS platform.