ESTABLISHMENT OF A QUALITY ASSURANCE FRAMEWORK METHODOLOGY FOR ADDITIVE MANUFACTURING CHEMICAL COATED SAND

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ABSTRACT

The Voxeljet VX1000 printing process uses a no-bake Furan process to directly manufacture sand moulds and cores for the foundry industry. The process requires a special chemical coated sand, which are currently being imported form the OEM. Localising the sand coating process could offer multiple advantages to local industry. However, no quality specifications are currently available for the coated sand which poses a risk towards both the foundry industry and AM manufacturing process. The purpose of the research paper is to theoretically define a quality assurance framework, in the context of a Quality Management System, and to explore the Quality by Design methodology to develop such a framework.

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1. INTRODUCTION

The Voxeljet VX1000 uses a Binder Jetting (BJ) Additive Manufacturing (AM) process to directly print or manufacture sand moulds and cores, which are mainly used in the foundry industry. The printing method uses a no-bake Furan process and is well-known and used in the traditional foundry industry. The traditional no-bake Furan molding process consists of a Furfuryl alcohol and acid chemical that are mixed with a refractory material. The mixing can be done by using either a continuous or batch mixer. After mixing, the acid acts as a catalyst for the Furan polycondensation process, which results in a Furan resin that will "glue" the individual sand particle together (Figure 1) [1].

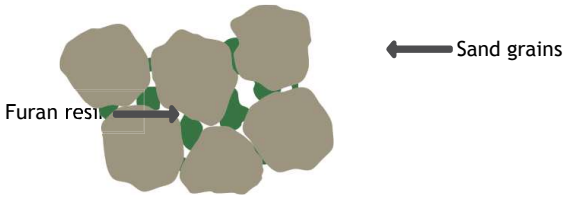

Figure 1. Sand-Furan bonding

Although the Voxeljet VX1000 uses a similar chemical process than traditional no bake Furan moulding methods, the technique used to mix the Furan, acid and refractory is different. The printing process selectively deposits the Furan binder on precoated acid sand layers to create the desired geometry of a part. An example of a printed sand mould component is shown in Figure 2. The precoated sand needs to adhere to a specific quality standard to ensure the reliability and repeatability of the printing process [1]. Due to this reason, both the Furan and precoated sand are supplied by the Original Equipment Manufacturer (OEM), to ensure that the consumables meet OEM quality requirements. Currently there are no South African service bureaus to provide the chemical coated sand and as a result it needs to be imported from the OEM in Germany. Localising the printing material could potentially decrease the printing cost while simultaneously creating local job opportunities and adds value to local raw materials.

Figure 2. 3D printed sand mould component [2]

However, this poses a risk to the quality of the printed components, as no quality assurance measures for chemical coated sand are available. Due to this reason, it is necessary to identify a method that can be used to develop the quality assurance framework to ensure that the coated sand adheres to the specifications of both the foundry (end-customer) and Voxeljet printing process. The purpose of the research paper is to theoretically define a quality assurance

framework, in the context of a Quality Management System (QMS), and to explore the Quality by Design (QbD) methodology to develop such a framework.

2. QUALITY MANAGEMENT SYSTEM

The industry's acceptance of implementing QMS has increased in recent years. This could be linked to the potential value that such a system can add to an organisation. According to literature, implementing a QMS can help a company to achieve and sustain a competitive advantage over competitors [3]. "Quality" has various meanings, but according to ISO 8402-1986 can be defined as "the totality of features and characteristics of a product or service that bears its ability to satisfy stated or implied needs" [4]. The ISO 9000 series of standards are among the most popular and well-known standards and were developed to provide guidance on how to implement a QMS with the aim to ensure products and services meet customer expectations. The standards included under the series are ISO9000, ISO9001, ISO9004 and ISO19011. ISO 9001 is the only standard in the 9000 series that requires certification and focuses on using of a process-based approach for implementing or improving the effectiveness of a QMS. A process-based approach is the systematic definition and management of processes to achieve a result, which aligns with the quality policy and strategic direction of the organisation. Thus, a process can be summarised as an activity used to transform an input to a desired result or output. A QMS could consist of a single or multiple successive processes, which enables [5]:

- Understanding and consistency in meeting requirements
- The consideration of processes in terms of added value
- Increase both performance and efficiency
- Improvement of process based on evaluation of data and information

According to ISO, there are six main components in a single process namely: source of inputs, inputs, activities, outputs, receiver of outputs and monitoring and measuring checkpoints. The monitoring and measuring checkpoints are specific to each process and will vary depending on the related risks [5]. A flow diagram of a single process, highlighting the interaction between the components, is shown in Figure 3.

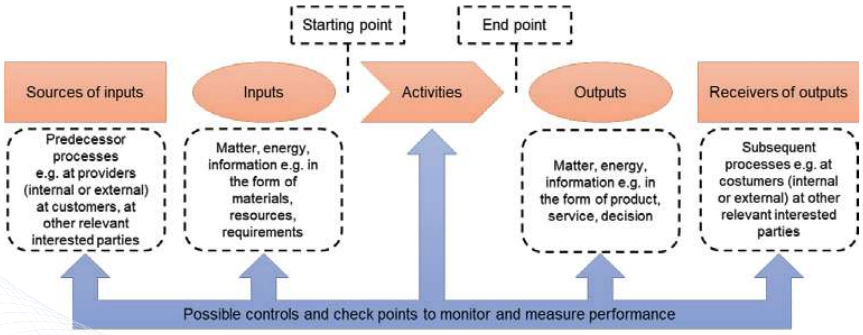

Figure 3.Process flow diagram [5]

ISO 9001 also highlights the importance of implementing a Plan Do Check Act (PDCA) cycle and is used as a process management tool. The PDCA cycle focuses on risk-based thinking, taking advantage of opportunities and eliminating or preventing undesired results and can be described as follows [5].

Plan – Establishing the objectives of the processes and resources necessary to deliver a product or service according to the customer's requirements and organizational policies, while simultaneously identifying risks and opportunities.

Do – Implementing the plan.

Check – Monitoring and measuring of the processes and products against the objectives, policies, requirements and planned activities and reporting of the results.

Act – Act on the results in the previous step, with the aim to improve the performance.

The ISO 9001 standard was developed around seven clauses and can be incorporated into the PDCA cycle (Figure 4). The "do" activity is seen as a quality assurance (QA) function that ensures that the activities are done correctly. QA is based on the principle of "doing thing right the first (and every) time" and is seen as a proactive process-focused activity.

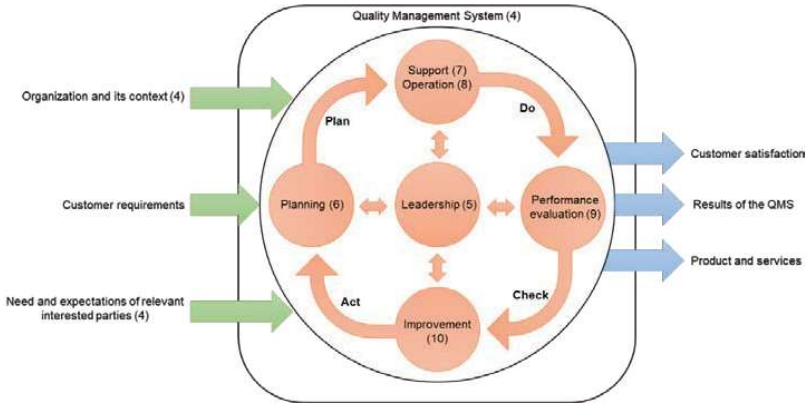

Figure 4. ISO 9001 PDCA cycle [5]

The "do" activity, shown in Figure 4, encapsulates both the support and operation clause of the ISO 9001 standard and is summarised in Table 1 [6]. Clause 7 focuses on ensuring that operational functions meet the quality requirements. These requirements could be determined internally or externally. The clause also highlights the use of processes, procedure and work instructions to ensure conformance.

Table 1. Summary of ISO 9001:2015 clauses 7 and 8

Clause 7 – Support	Clause 8 – Operation
Clause 7 is structure around support functions, which include: • Determine and provide the required resources to implement and improve a QMS system. These resources include human resources, infrastructure and work environment needed, maintenance, organisational knowledge and the competence of people.	Clause 8 specifies process requirements of operations and highlights the flowing crucial requirements: • Organisational planning and control processes, which emphasize how a company understands, communicates and meets customer requirements. • Design and development reviews requirements – verification and validation should be planned from the start. • Purchase and outsourcing processes.

• Ensuring management and staff are aware of the quality policies and relevant objectives. • Implement a document control system.	• Design and development processes. • Specify controls for actual production and service provision. • Delivery and signoff requirements. • Nonconformance processes.

3. PROCESSES, PROCEDURES AND WORK INSTRUCTIONS

Although ISO 9001:2015 has relaxed the strict requirement for quality management documentation, to satisfy the remaining documentation requirements, and (often more important), to properly implement the QMS, Processes, Procedures and Work Instructions are typically still employed [7]. Processes, procedures and work instructions are considered to be QA measures as they ensure that the planned activities are done correctly. The relationship between processes, procedures and work instructions could be explained by organising them into three tiers, as shown in Figure 5.

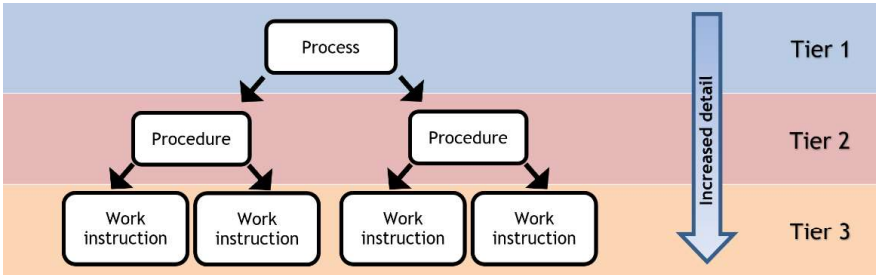

Figure 5. ISO 9001 Process, Procedure and Work Instruction

- **Tier 1 - Process**

  As mentioned in the previous section, processes play an important role in the ISO 9001 standard. A process is an activity that transform an input into an output, aligns with the quality policy and strategic direction of the organisation, and is seen as a high-level strategic method of control, which summarises the objectives, specifications and broad resources needed [7]. A simplified representation of a process is shown in the figure below:

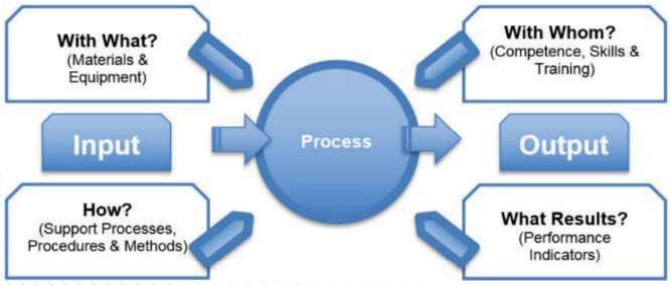

Figure 6. Process layout

- **Tier 2 - Procedures**

  A procedure is a uniform method that specifies how to perform a process. Using procedures will ensure that the operation is repeatable and accords with to the

required quality standards. There are no fixed document layout requirements, however the following elements are deemed to be important when compiling a procedure document [7]:

- Purpose of the procedure – Why is the procedure important?
- Procedure objectives – What needs to be accomplished and how will it be executed?
- Responsibilities – Who needs to perform what action?
- Instructions on how to perform a process – how to convert the inputs into outputs
- Locational requirements – Where should the activity be performed?
- Important criteria that should be met.
- Tools, information or other resources required.
- Terminology, definitions, explanations, etc.

➢ **Tier 3 – Work instructions**

A work instruction specifies how to perform a certain task within a procedure and is usually a step by step instruction. Work instructions are only necessary when more detail is required for a task listed in the procedure and is not necessary for each task point [7].

4. QUALITY BY DESIGN

The QbD methodology was identified as a suitable methodology to aid in the development of a QA framework for the chemical coated sand process. The QA framework could serve as a basic structure to develop process, procedure or work instruction documents. QbD was originally introduced in 1985 by Juran's book "Juran on Quality by Design" and is based on the Trilogy approach that describes the requirements to achieve breakthroughs in new product, service or process development. The methodology is widely used by both the automotive and pharmaceutical industries and is also known as concurrent, simultaneous or parallel engineering, since all the major development functions are required to be performed at the same time. The difference between traditional and QbD product development is shown in Figure 7 [8].

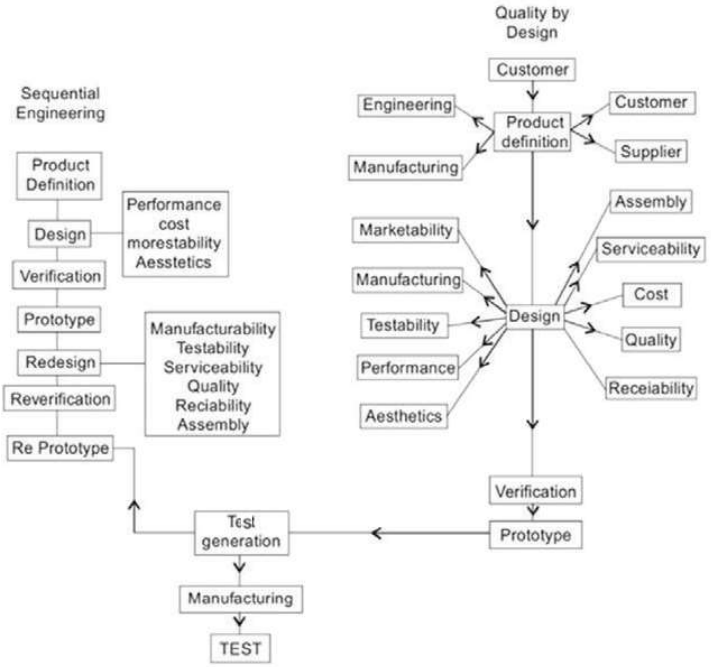

Figure 7. Product development flow diagram [8]

Product development, using the traditional manufacturing principles, includes multiple changes and evaluations to the part, or service, to achieve the final product. In the pharmaceutical industry, early stage designs can consist of 70% of the total product lifecycle and influence approximately 70% to 85% of the total product cost. The major contributor towards the increase in the total product lifecycle and cost is due to the risks involved during the development stage. Thus, QbD is used as a tool to reduce risks and foster rational design thinking to avoid trial-and-error situations. This has proven to reduce both research lead times and development costs [9]. The QbD methodology comprises of 8 sequential steps to create a better understanding of a product/service and its manufacturing process, which includes the identification and control of all the variables to ensure quality. The methodology's process flow is demonstrated in the figure below:

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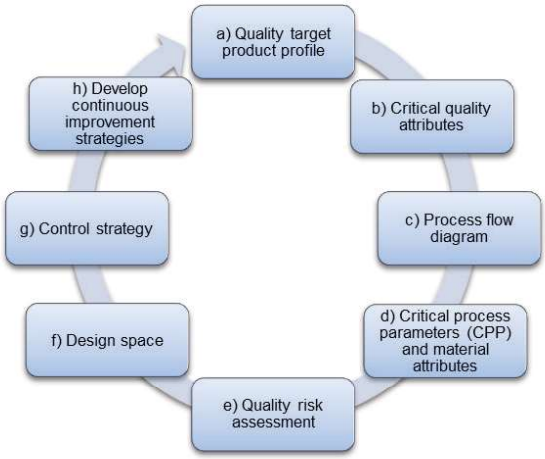

Figure 8. QbD framework

a) Quality target product profile (QTPP)
The QTPP describes how a product will be utilised by the end user, which include product information such as the ideal characteristics and features in relation to the safety and performance of a product. This will link the development process to a clear goal. The profile can be developed using the expertise from multiple professions, for example: marketing (defining the end user's needs), engineers, market specialists, etc. However, it should be noted that the QTPP is a dynamic process that incorporates the feedback of all the QbD steps. Garvin (1984) stated that quality can be divided into five approaches and is defined based on the end-user's perspective [9]. These approaches are consider to be high level approaches and include:

- Transcendental perspective - a metaphysical aspect of quality, which makes it very hard to define. For example, when a client uses a certain brand of cosmetics and feels pretty but cannot provide any physical proof [10].
- User-based view - when a product satisfies a specific target group's preference. This approach is based on quality as defined by the end user [10].
- Manufacturing-based - relates to the production and engineering requirements. The following approach defines quality from a manufacturer's point of view, which includes aspects such as product specifications, requirements, available technology, reducing scrap rates, etc. [10]
- Value-based - can be defined as the quality level perspective from the price and other attributes. In other words, the value a client associates with a certain product cost. [10]
- Product-based - When the quality can be assessed by quantifiable and measurable characteristics or attributes. This approach does not necessarily satisfy a specific customer's need but rather answers a specific question. An example might include the time it takes for a computer to start? [10]

b) Critical quality attributes (CQA)
This step identifies the product characteristics which should be contained within certain limits to ensure that they conform to the desired quality level, defined in the QTPP. Examples of CQA attributes include, but are not limited to mechanical, electrical, biochemical, etc. functions. A scientific or risk management rationale are usually being used to effectively identify the product characteristics. However, the CQA are only identified but not defined within limits, for early product development phases [9].

c) Process flow diagram (PFD)
The PFD helps to represent processes visually through the identification of the necessary steps, participants and decisions in a process. The PFD improves the understanding of the current process and helps to identify problem areas that might affect the product performance and CQA. It also helps to achieve a more accurate identification of the most critical processes [9].

d) Critical process parameters (CPP) and material attributes (CMA)
This step is aimed at determining the process parameters and material attributes whose variability could potentially affect CQA. Usually the CPP and CMA should be monitored and controlled throughout the process to ensure process consistency, repeatability and accuracy. The attributes could be determined using a scientific or quality risk approach by linking the QCA groups (Step 2) to each of the processes mapped in the workflow map (Step 3) [9].

e) Quality risk assessment (QRA)
The QRA identifies and controls potential quality risks during the development and manufacturing process to ensure a high-quality product. An Ishikawa diagram could be used to identify and group the major influencing factors for a given problem, where after a FMEA could be used to identify potential failure modes, determine their effect on the operation of the product and identify actions to mitigate the failures. Any factor with an uncertain probability of occurring can influence the outcome of a project and is considered to be a risk or hazard [9].

f) Design space (DS)
The design space describes the link between process inputs and critical quality attributes. Thus, it is used to determine the multidimensional combination and interaction of input variables (e.g. material attributes and process parameters) that have been demonstrated to provide the assurance of quality. The DS defines the critical parameters and limits, identified in Steps 1-5, to ensure an acceptable quality product [9]. A well-defined DS results in repeatable product performance across different manufacturing batches [11].

g) Control strategy (CS)
The control strategy will list the required monitor or control actions to ensure that the processes will remain within the predefined critical process parameter and material attribute range. There are several control strategies available, which include but are not limited to: procedural control, in-process controls, batch release testing, process monitoring, characterization testing, comparability testing and consistency testing [12].

h) Continuous improvement strategies (CIS)
CIS will list a plan with activities designed to bring gradual and ongoing improvement to products, services or processes through constant review, measurement, and action. Deming Cycle or Kaizen are well-known strategies used to support continuous improvement actions [9].

5. CONCLUSION

The purpose of the paper was to theoretically define a quality assurance framework, for the local production of chemical coated sand used in Additive Manufacturing applications, and to explore the QbD methodology to aid with the develop such a framework. The framework could be used as a basic structure to develop process, procedure or work instruction documents, necessary for a QMS and will ensure the coated sand adheres to predefined quality standard. The quality standard that should be developed needs to address both the foundry's and AM process' requirements. The QbD methodology was identified as a suitable method to guide the development process and is based on the Trilogy approach that uses a concurrent engineering approach to reduce risks, foster rational design thinking and eliminating the trial-and-error development approach. Future research work will include applying the QbD methodology to the sand coating process with the aim to develop a QA framework.

6. REFERENCES

[1] **Woods, K.** 2018. *Sand distribution effects on three dimensional printed sand properties*. Lowa: University of Northern Iowa.

[2] **Metal resources**. 2017. *Unlimited possibilities by making sand molds and cores with 3d printing technology*. https://www.ressourcesmetallurgiques.com/unlimited-possibilities-making-sand-molds-cores-3d-printing-technology/. Date of access: 22 January 2019.

[3] **Kibe, E.N. & Wanjau, K.** 2014. *The effect of Quality systems on the performance of food processing firms in Kenya*, IOSR Journal of Business and Management, 16(5), pp 61-72.

[4] **Quality**. 2018. BuisnessDictionary. http://www.businessdictionary.com/definition/ quality .html, Date of access: 26 June 2018.

[5] **ISO.** 2015. Quality management system-Requirements. Switzerland.

[6] **9001Council**. 2017. A summary of ISO 9001:2015. https://www.9001council.org/iso-9001-summary.php. Date of access: 25 January 2019.

[7] **ISO 9000 store**. n.d. Processes, Procedures and Work Instructions. https://the9000store.com/iso-9001-2015-requirements/iso-9001-2015-context-of-the-organization/processes-procedures-work-instructions/. Date of access: 13 December 2018.

[8] **Naidu, N.V.R., Badu, K.M. & Rajendra. G**. 2013. Total Quality Management. New Delhi: New age international publishers.

[9] **Martinez, D., Mirnajafi, A., Carty, C.P. & Stewart, R.A.** 2018. Application of quality by design for 3D printed bone prostheses and scaffold. PLoS ONE, 13(4).

[10] **Ross, J.E.** 2009. Total Quality Management. https://totalqualitymanagement.wordpress.com/2009/08/27/definition-of-quality/. Date of access: 25 October 2018.

[11] **Peltonen, L.** 2018. Design Space and QbD Approach for Production of Drug Nanocrystals by Wet Media Milling Techniques. Pharmaceutics, 10(3):104.

[12] **Chavan, S.D., Pimpodkar, N.V., Kadam, A.S. & Gaikwad. P.S.** 2015. Quality by Design. Journal of Pharmaceutical, 1(2) pp18-24.