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Requirements for Medical Plastics – Launch of new Guideline

Prof. Dr.-Ing. Stefan Roth, Prof. Dr.-Ing. Thomas Seul, Schmalkalden University of Applied Sciences, Schmalkalden, Germany

Abstract

Safety for patient and user is an essential requirement for medical products. Subsequently, plastics grades used in medical have to fulfil particular requirements, i.e. constant properties, formulation lock or biocompatibility. Surprisingly, no standard has existed to define the requirements for medical grades so far. This gap has been filled recently by the new guideline VDI 2017 developed and launched by a work group of the German Engineer's Society (VDI). This article addresses the development of the new guideline and presents the essential requirements to be covered by a medical grade.

Introduction

Since user and patient has to be subjected to any risk by a medical product, highest attention has to be paid to safe design of medical products. Therefore, legislation frameworks have been established in most countries like the medical device regulation MDR 2017/745 [1] within the European Community or by law, i.e. Code of Federal Regulation 21 CFR 820 [2] for the US-market. All these legislative works have in its common sense to reduce the risk to patient and user by medical products to a level as low as possible. Maintaining stable and consistent product requirements all stages of production and over life time of the product are regarded as core characteristic of medical products to guarantee stability in quality of product with the purpose of products safety for patients.

Thus, selection of appropriate material for products in medical application is regarded as one of the most crucial points in the development process. Therefore, materials for medical have to meet design needs such as mechanical, thermal and chemical requirements as well as special demands to biocompatibility, that have been described in depth by the ISO 10993 standard "Biological evaluation of medical products" and adapted for the US-market by Food and Drug Administration (FDA) [3].

The share of plastics going to medical industry is approximately 1 - 2% of the annual production in total which is comparatively small in comparison to the demand for other branches like food packaging or construction. However, in total it is found to be a considerably amount of at least 500.000 tons per year only in Europe [4]. Facing these enormous figure and taking the growing importance of the medical sector into account, surprisingly neither national nor international standard or guideline exists so far to describe the requirements to polymer or plastics grade with regard to medical application.

In practice, when it comes to material selection during the development process, the designer tend to orient to "medical grades" that are offered as such by the materials manufacturers and distributors. For these grades, proof of biocompatibility of the granule according US or European guidelines is provided by the material supplier. This indicates the medical device manufacturer that this material is expected be suitable in general. However, it is under the obligation of the manufacturer to proof his product requirements such as biocompatibility at the final product that has been undergone all steps of processing. Up to now, no US or EU guidelines or standards exist for clearly defining the medical grade plastics (MGP).

Here, we face a gap in standardization the needs to be filled and hence represents the trigger for the development of a new guideline in that field by a working committee of the German Engineer's Society. The approach to the guideline, its process of formation and the key points of this work are described in the following.

Starting Point for Development

The German Engineer's Society has a long lasting tradition in development of general recognized technical rules and standards for all kinds of technical areas. From its essential ideas, guidelines are developed by a technical committee of experts in a technical field where no national or international standard has been established so far. Technical experts come together in order to discuss and develop a guideline that is afterwards published in a first draft version as so called "green print". The green print can be regarded as a draft) that can be commented by the public, respectively interested person within a limited time (6 - 12 month). The expert committee deals with every comment or objection and decides finally for modification of the guideline or rejection of the comment. After this period the final version is published as "white print" and undergoes periodic review every five years.

The scope of the guideline VDI 2017 "Medical Grade Plastics" [5] comprises the applications of medical products, pharmaceutical packaging, in vitro diagnostics and active implantable medical devices. The guidelines committee, set up of material manufacturers, medical

product manufacturers, distributors, notified bodies and Schmalkaden University of Applied Science commenced its work in January 2017. Already 12 months later, the green print was published and has undergone the phase for commenting. The final white print is expected to be due by Spring 2018.

Outline of the Guideline

The basic outline and content of the guideline is given with by the following structure:

1. Scope of the directive
2. Terms: general, materials, parties involved
3. Abbreviations
4. Definition Medical Grade Plastics (MGP)
5. Regulatory requirements for MGPs
6. Consistency of formulation
    a. Scope and definition for formulation of a MGP
    b. Requirements for consistency of formulation
    c. Assessment of consistency of formulation
7. Information and documentation
8. Security of Supply
9. Change Management
10. Packaging, storage and logistics
11. Customer-Supplier relationship
12. Appendix
    a. Example for Quality Agreement (QA)
    b. Example for risk assessment
    c. Example for declaration of conformity for MGPs
    d. Risk factors in processing of material [6]

Following items of this guideline have to be highlighted since they represent requirements and needs with highly impact on medical grades, such as

- **Consistency of Formula**tion (fig. 1),
- **Security of Supply** (fig. 3),
- **Change Management** (fig. 2),
- **Quality Agreement** as key role document between customer and material supplier (fig. 4).

The Consistency of Formulation is regarded as the essential requirement for constant properties. It means on one hand consistency of formulation in its content share, components and raw material suppliers used and, on the other hand, consistency in the material manufacturing process. Corresponding documentation on formulation consistency has to be presented to the customer on request. It is well noted that this information is considered as highly crucial since it represents an essential part of the intellectual property of the material supplier. However, for example, evaluation of biocompatibility by medical product manufacturer may necessitate essential information on formulation. Information transfer has to be covered by corresponding non-disclosure agreements.

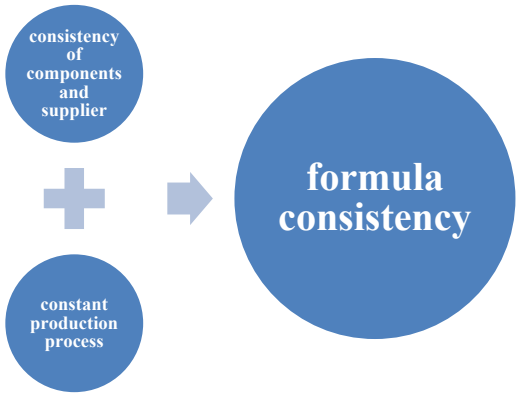

Figure 1. Constant process and formulation is an important requirement for constant properties.

Changes that affect consistency has to be evaluated by the raw manufacturer and corresponding information has to be hand over to the customer within a described process of change management. The installation of a change management process builds therefore another column of medical grade requirement.

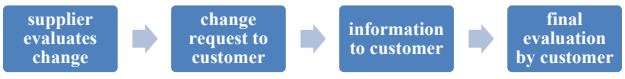

Figure 2. Change Management Process. By passing on information to the customer, supplier ensures information flow from manufacturer to distributor respectively customer.

The aspect of maintaining the security of supply has to be kept in mind to ensure a safe and stable supply of the customer with medical products. Material suppliers have to make extraordinary precautions for that (see fig. 3). The new guideline provides appropriate requirements for that by defining terms like **Notification of Change** from supplier to customer (in case of incident), **Pre-Notification Period** (availability of current material formulation after announcement of change, typically 24 month) or **Last Order Call** (possibility for last ordering of stock before material change, 12-month supply recommended). Furthermore, a concept of Security of Supply, for instance by safety stock or alternative production line (2nd source) is mandatory for material supplier.

Figure 3. Security of Supply: measures addressed by the guideline.

The requirements described here in detail and further ones mentioned by guideline can be agreed upon by set up of a quality agreement between material supplier and customer. It acts as a central key document, that lists the essential information and agreements upon the medical grade between both parties.

Figure 4: Content items of the Quality Agreement.

A good practice example for a quality agreement is added to the guideline for demonstration purposes.

Discussion

All along its work, the committee has born in mind to establish a widely accepted standard that can act as a guideline as well for material suppliers as material customers. It should describe the standard and basic requirements a medical grade is expected to bring with it when declared as intended to be applied for medical application. On one hand customer get information what to expected from on the other hand material supplier knows by the guideline about the requirements to be fulfilled by its grades.

Since this guideline has the intention to cover a broad range of products and application from pharmaceutical packaging, in-vitro diagnostics up to medical devices from low to high risk classification, it follows the principle to bring all requirements for a medical grade down to the least common denominator which specifies the base in specification applied to the medical grade covering all fields described below. Additional requirements or enhanced, more tight conditions for plastics grade should be arranged between the parties involved on a bilateral base on demand, i.e. if application makes it necessary. Since presentation of the green print with focus on the medical market Europe [7], the guideline has gained acceptance by affected parties and stakeholders already. Bearing in mind, that no corresponding standard exists so far, the committee is looking forward to the reaction of the public to the standard in the United States, that represents the most important market in medical.

For future prospect, it seems to be likely that other industries also dealing with high risk application, e.g. aeronautics or automotive, may adopt this given standard now, since the also require constant material properties for safe products providing constant and safe performance. Hence, this guideline will act a pacemaker in regulation for plastic materials in all field of industry that require high safety standards.

Conclusions

Clarity creates security. It can be expected that the above-described definitions and requirements by the VDI Guideline “Medical Grade Plastics” will set a standard that has been already highly overdue in industry.

In a strictly regulated environment such as that is conventional and necessary in medical technology, the guideline, which is to be understood as a code of practice, forms an aid for everyone involved in the manufacturing process.

References

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