



European Biotechnology

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Interview

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on his firm's
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Clean surfaces, clean process

STAINLESS STEEL OPTIMISATION A pilot study looked at the role of optimised steel surfaces for contamination-free large scale biotech processes. Cornelius Mauch, CEO of Bolz Intec GmbH in Argenbühl, Germany, told EUROPEAN BIOTECHNOLOGY about the impact of the findings.

EuroBiotech One aim of cleaning stainless steel tanks used for biopharmaceutical production is to prevent contamination of batches due to the carry-over of particles. Bolz Intec has investigated the adhesion behaviour of particles to stainless steel. What are the most important results?

Mauch The surface properties have a decisive influence on the chemical and physical properties of stainless steel. In critical areas such as the food and pharmaceutical industries, technical terms such as EHEDG (Hygienic Design) and GMP are becoming more and more important. The background is that operators want to avoid the spread of particles and the associated contamination of their batch as much as possible. One of the decisive factors here is the cleaning behaviour of surfaces and the associated adhesion behaviour of particles. But which factors influence the adhesion of

particles to hygienic surfaces and how can these factors be optimized? Bolz Intec from Eisenharz/Argenbühl, which has been producing drums, funnels, pressure vessels and customized constructions from chrome-nickel steels for decades, asked itself exactly these questions and has examined the properties of surfaces in several years of research in cooperation with the University of Konstanz (HTWG). In addition to the usual roughness profile of surfaces, which is currently used as the main feature in the description of surface quality, attention was paid to other factors such as their topography, morphology and surface energy.

EuroBiotech What quality factors were you able to identify?

Mauch We found out, that roughness Ra in μm is not the only quality factor. The standard grinding process removes the mill scale from the cold rolling process in the steel mill. This outer surface is already smooth but contains residuals like sulfur, therefore, it must be removed. But the mechanical grinding creates other issues such as caverns, folded microlayers and of course the typical grinding direction, which looks like a plowed field in the scanning electron microscope. Besides that through grinding you create heat flashes that affect the steel qualities. Therefore you want not only a smoother surface but a homogenous surface. This is achievable only through a softer grinding over a longer period of time. Without a well prepared grinded surface the following steps of electro polishing and passivation cannot be maximized to their potential.



CORNELIUS MAUCH, Managing Director of Bolz Intec GmbH. After graduating from Witten with a degree in economics, Mauch gained management experience in the areas of sales, marketing, purchasing and controlling at well-known national and international companies. Before taking over the management of Bolz Intec GmbH in July 2015, he worked for FTI Consulting Deutschland GmbH as Senior Director in the operational transformation team. Mauch is a member of the German Association of Materials Management, Purchasing and Logistics and of the International Society for Pharmaceutical Engineering as well as the Junior Chamber of Commerce.

EuroBiotech How can your investigations of the surface topography be used to achieve better surface properties?

Mauch Bolz Intec has made use of the knowledge gained from these investiga-

tions and developed a process in which the previously mentioned, low, constant removal is achieved partially automatically over a long period of time. The process was titled *Optimized Grind Finishing* or *OGF®* process. The abrasion in the container is achieved with geometrically indeterminate grinding tools, which move inside the container. The great advantage of this process is that the surface, in addition to its outstanding quality, is reproducible. You are independent of indefinite variables, such as the manual contact pressure during conventional grinding by an employee or the quality of individual abrasives. Important for Bolz Intec was an end result with a defined, extremely fine roughness depth (R_a up to $<0.1 \mu m$) with little depth influence on the structure and a homogeneous surface with a pronounced passive layer.

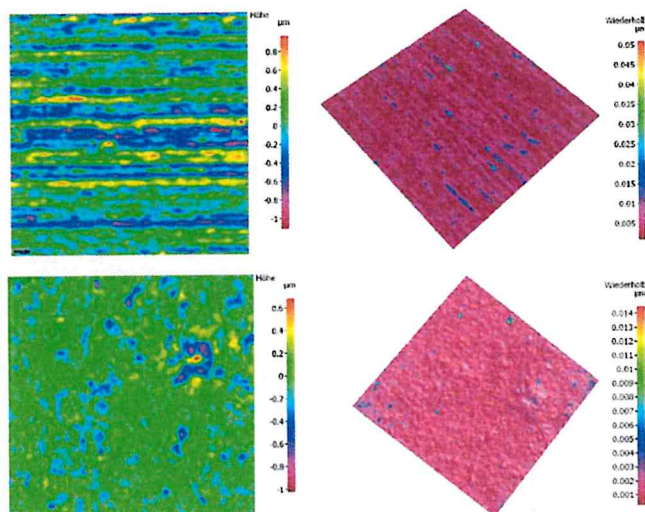
EuroBiotech_What are the first results with the newly used grinding process OGF?

Mauch_State of the art is the current assessment of surfaces with non-destructive tests, such as roughness measurement in connection with an optical test. But in addition to these, there are other criteria that should not be disregarded. Among other things, the way in which the surface is refined should be consid-

ered. They found out, that different grinding methods in the final evaluation of the surface show different adhesion behaviour, although the (R_a in μm) value of both surfaces is the same. It is now clear that the way in which the material is removed, play an important role here. As an experiment, contrary to the usual manual grinding, the container was ground with a partially automated grinding process over a long period of time. This fine removal over a longer period of time resulted in significantly less adhesion and thus better cleaning.

EuroBiotech_What further investigations do you consider necessary and what do you want to achieve in the medium term? **Mauch_**Our goal is to provide the world's best stainless steel surface for customers in areas with very high requirements e.g. biotechnology. This includes not only a smooth surface but also an electrochemical removal and an additional treatment to maximize the passive layer. Powders and also some liquids behave very differently. Therefore in the medium term we want to design a customized surface quality that is optimized for the individual products in terms of adhesion, time to clean and maximum discharge / removal of the valuable API.

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3D representation of the mechanically finished surfaces. Above conventional grinding technology, below Optimised Grind Finishing process (OGF).

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