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GOOD MANUFACTURING PRACTICE OF TATTOO INKS IN EUROPE**Ralf Michel¹**¹*Deep Colours! GmbH the inkfactory; (Neuburg am Rhein, Germany).*

Tattoo inks in Europe are so called borderline products, non regulated by cosmetic or medical device directive.

As the product is injected under the skin, it is not a cosmetic product. The fact that it is implanted in the skin, stays there for more than 30 days and gets in contact with the blood and lymphatic systems indicates that it is close to a class IIb medical device.

Manufacturing safe tattoo inks will follow similar GMP guidelines like sterile pharmaceutical products or sterile medical devices class IIb. An established quality management system, regulations about personnel and the premise and equipment is required.

The documentation, the production and the quality control will guide the manufacturing of safe products. Outsourcing of activities, contract manufacturing and analysis by third parties needs to be regarded.

To ensure a continuous improvement of the product it is important to handle as well complaints about the product and manage product recalls in case of serious problems. Finally self inspections should be done to check the functionality of the quality system.

Production of safe tattoo inks will follow such guidelines and will ensure best consumer safety.