GMP in Cosmetics: National and International Aspects

SWISS SCC Training Event, 24th September 2004 in Olten, Switzerland

The topic of GMP, the Good Manufacturing Practice was in the center of this year's training event of the SWISS SCC. Moderated by **Dr. Hans-Jürg Furrer** more than 50 participants listened to excellent presentions in the morning and actively applied their new knowledge in the afternoon during a workshop to gain practical experience.

NATIONAL – Switzerland

Dr. *Michel Donat* from the Health Ministery of Switzerland highlighted Swiss aspects of GMP in cosmetics. There is no legel GMP regulation / guideline for cosmetics in Switzerland. Neither the cGMP for pharmaceuticals nor the approach / guideline of HAACCP (Hazard Aalysis and Critical Control Point) in food sector is valid for cosmetics. Nevertheless in chapter 3 of the food regualation 817.0 a clear advise exists for the principle of self control. Therefore also cosmetics have to obey the Good Manufacturing Practice and even a legal audit does not release from the duty of self control. Export products are accompanied by certain export certificates. Certain countries require additional certificates and an additional legalization from the BAG as i.e. a BSE certificate, which will only be issued exceptionalwise. In his summary Dr. *Michel Donat* would appreciate for Switzerland specific tailor made GMP guideline for cosmetics as reference, but clearly differentiating from the HACCP (food) und current GMP (pharmaceuticals). From raw material entrance up to the finished product in export, all parameters of product quality should be recorded from human, technical und administrative point of view. For Switzerland a more not legal wise binding »soft law« could get valid. At present there are a lot of negotiations, which variation (ISO or European Commission) will get valid in the EU. **Dr. Michel Donat** thinks it to be more adequate to adapt the ISO variation in Switzerland, but it should be avoided to create a special case.

INTERNATIONAL – EG / Germany

The second presention concentrated on Germany and Europe, excellently presentated by *Hans-Peter Gesell* of the HPG Consulting/Germany. Since 1997, the enforcement of the 6th Amendment, clear requirements on European level exist for cosmetic GMP, but till now legalwise there are no clear implementation statutes. In article 7a, point c of the 6th Amendment the good manufacturing practice is required. The actual law permits a huge moving space not differentiating between huge or small companies and is valid for all cosmetic product categories. The manufacturers have to obey the cosmetic GMP rules in all departments of manufacturing, also assuring an adequate professional qualification of the person responsible for production. Based on present existing guidelines, specific requirements exist as i.e. for personnel, the facilities, the technical equipment, the plant hygiene, the raw materials, the manufacturing processes, the quality control and the documentation. Since 1994 various publications exist from DIN ISO 9001, guidelines of cosmetic GMP, checklists for self control and additional specific recommendations from the IKW (German Association), Colipa (European Association for cosmetic companies) and from the Council of Europe.

According to **H.P Gesell** the DIN ISO 9001 does not replace cosmetic GMP, as the DIN ISO 9001 does not give any or only marginal support enforcing the specific requirements of a cosmetic production facility. To obey the ISO has no influence on the product quality, as the certification according DIN ISO 9000 ff only confirms the existence of the there required written directions.

The proceeding action of the control authorities in the various countries of the EU is due to missing implementation statutes still very different. Based on experience-values of the manufacturer in Germany the authorities of the countries perform their audits, not differentiating between huge, medium or small companies. In future **H.P. Gesell** could imagine an enactment of cosmetic GMP guidelines from the EU with the advantage of a unique reglementation in all EU countries, but the disadvantage of more rigid requirements. Nevertheless a harmonisation of the existing cosmetic GMP guideline in the different countries is to aim at with on longer term moving much closer towards the GMP guidelines in the phamaceutical industry.

***Picture:** Auditorium*

INTERNATIONAL – USA

Dr. Marion Fröschle shared her knowledge of US with the participants. The congress in USA has passed 2 basic laws for

Picture: *Intensive concentration of the participants at the workshop was required*

cosmetics: the 1938 enforced Federal Food, Drug and Cometics Act (FDCA) and the 1967 enforced Fair Packaging and labelling Act (FPLA). Title 21 of the Code of Federal Regulations (CFR) regulates all cosmetics, 1960 amended by the Color Additive list and 1972 by the OTC Drug Listing ACT. In US, OTC (Over the Counter) products are regulated within pharmaceutical law – and within this category also the so called cosmetic-drugs. The ingredient in the formula (OTC Monograph), the intended use and/or the claims on packaging are decisive to regard a cosmetic as cosmetic or as OTC/cosmetic-drug product according US law FDCA ACT. Cosmetic products as i.e. a care-day cream with SPF 15, have to obey both regulations (cosmetics and OTC). Ref. distribution level meaning OTC drugs are not restricted to specialized stores and may be sold in any type of retail establishment. The office of Food and Drug Administration (FDA) is in US the responible ministery with the department CFSAN = Center for Food, Safety and Applied Nutrition for cosmetics and the department CDER = Center for Drug Evaluation and Research for OTC/Cosmetic-Drug products. In US based on 21 CFR 210 & 211 all from the CDER regulated drug products – and therefore also all OTC/cosmetic-drug products – have to be produced according to much stricter currrent GMP. Transparency and back tracing of the total production process incl. i.e. R&D, marketing (labeling, claim), export and ref. process validation of computerized/automatic processes have to be assured. For OTC/cosmetic-drugs, the manufacturing-/production facility and the products (incl. label copy of the selling version in US) have to be registered/notified and an own agent (citizen of US) has to be announced for the FDA. The registration of OTC products in the US is regulated under the penal law. The production facility (incl. i.e. packaging and store) can be audited – when required – by the FDA according current GMP, taking samples for investigation. Till now inspections have not been very probably. Based on 11th of September 2001 and a big amount of money released from the congress to the FDA to assure safety issues they get however much more realistic. Based on the OTC Labeling and Sun Monograph an increased investigation of imported products with i.e. sunfilter (SPF claims) is foreseen. Nevertheless, in general the topic of an import barrier should also be taken into account when looking at increased regulatory requirement ref. trade relations between countries.

INTERNATIONAL – Asia

Pierre Bottiglieri of PAP Cosmetic Sciences S.A. entered into details of the GMP situation of the far east countries. ***ASEAN***, the Association of the southeast nations (Brunei Darussalam, Cambodia, Indonesia, Laos, Malaysia, Myanmar (ex-Burma), Philippinen, Singapore, Thailand und Vietnam) was established 1967. Since 1997 ASEAN is on the way to become one single market with about 500 Mio consumers. ASEAN Guidelines to cosmetic GMP are published and are similiar to EG. In ***China and Honkong*** no GMP standard exists. All production facilities have to apply for a licence, called »productions-license«, valid for 5 years. Special licences have to be applied ref. OTC products. In ***India*** Guidelines for cosmetics are observed by FDA India with reference to Drugs and Cosmetics Act (1940) and Rules (1945), both continously amended when required by Government notifications. The »manufacturer-licence« is valid for 2 years. The ***Japan Industry Association*** (JCIA) published in 1980 a self regulation on GMP, which is currently under process of reviewing in order to change the content drastically. It is supposed that the corresponding revised draft shall be available till end 2004. In ***South-Korea*** cosmetic GMP is the so called »Enforcement Regulation«. In ***Taiwan*** is no GMP standard. Cosmetic factories have to meet the standard of some specific pharmceutical regulation in order to apply for a licence which is a »Certificate of cosmetics manufacturing«.

The ***Asean market*** is of special interest based on the huge amount of consumers of almost 3 billions of people (ASEAN 500 millions, China 1.3 billions, India 1 billion, Japan 130 millions, South-Korea 50 millions, Taiwan 20 millions), which means almost half of the total world population (6.4 billions).

The afternoon was opend by ***H.P. Gesell with the topic »cosmetic GMP in practice«***. The product quality is not only influenced by the production facility, but also by the departments of purchase, research and development, the finance, marketing, quality assurance, further technical departments and the board. All employees of the company are responsible for the product quality. Complete specifications with reliable tolerances are an important pre-condition for the product

Picture: *Moderator/Speakers from left to right: Dr. Hans-Jürg Furrer, Pierre Bottiglieri, Dr. Marion Fröschle, Walter Scheffel, Hans-Peter Gesell, Dr. Michel Donat, Dr. Hans Zulliger*

quality, a coordination between customer and supplier is necessary. The purchase sector has a key role: It is responsible for costs, the quality and the delivery time. At least 1 x/year a self control of the factory should take place by internal audit or by external consultants with an adequate action plan. Recommendations for measures of reconstruction respectively sanitation especially deal with the right property of ceiling, walls and flooring for an easy but effective desinfection.

The theorectically gained knowledge was approved in the following workshop. Guided by 3 case studies, the participants as fictitious quality responsibles had to take decisions and actions under the direction of the ***SNV (Schweizer Normen Association) Dr. Hans Zulliger/Cilag AG und Walter Scheffel/Cilag AG***. Based on various informations and test data, a raw material or i.e. a product had to be released or to be blocked. Detailed knowledges and the comprehension of HPLC measuring values and refering validation of colums have been of relevance as well as the exact investigation and compliance of methods, the regulations of valid signatures and existing – or missing – training qualifications of the fictive employees. At the final end all cases have been solved, prepared and presented in an excellent way by the different groups. The participants could – beside a lot of intensive personal contacts – take back to work an increased national and international knowledge of cGMP and already practical experience, gained in this fascinating training course.

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