



# SwAPP

Swiss Association of Pharmaceutical Professionals

## SwAPP Newsletter Q2 2010

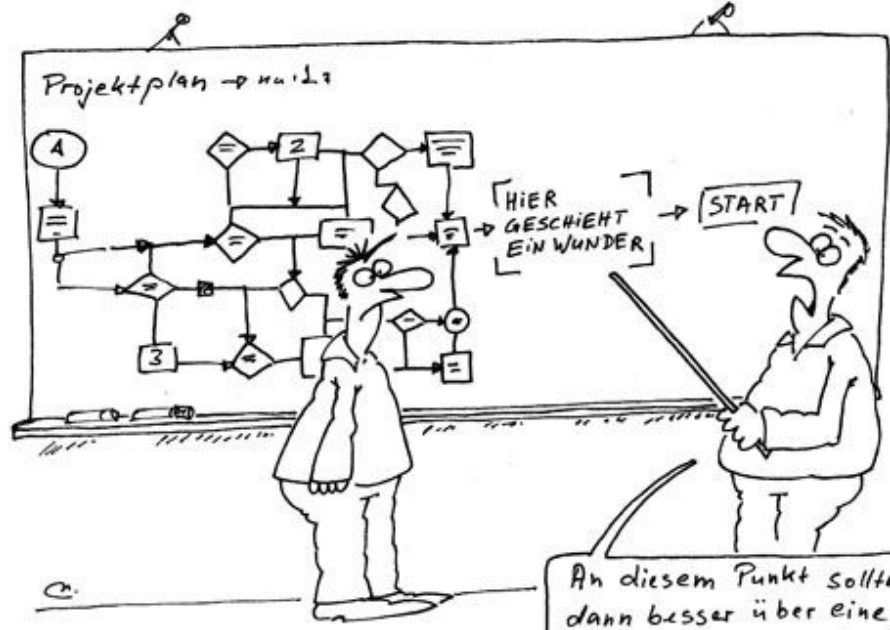
<b>Editorial</b>	<p>Dear SwAPP member</p> <p>Welcome to the second SwAPP Newsletter! The year 2010 started with an exciting SwAPP event. Over 130 participants attended our Exchange Expertise Workshop in Bern. Please read more about this successful event below.</p> <p>Also, we would like to thank you for attending our General Assembly and for actively providing your input and comments. It is with your ideas and suggestions that SwAPP can develop into a more and more successful professional organisation which fulfils the needs of its members.</p> <p>Urs Gasser</p>
<b>Impressions from SwAPP Events</b>	<p>The 3<sup>rd</sup> SwAPP Exchange Expertise Workshop took place on March 18 at Bern Westside. The highlights of this event were:</p> <ul style="list-style-type: none"><li>• Introduction on non-interventional trials Dr. M. von Poncet, Janssen-Cilag AG</li><li>• Panel discussion on non-interventional trials, with experts from Swissmedic (Dr. F. Jaquet / J.-C. Méroz), AGEK (Prof. R. Maurer) and Pharmaceutical Industry (Dr. P. Kleist) Chairman W. P. Hölzle, vips; see also below for more details</li><li>• Workshop on latest news on regulations in clinical trials, with Swissmedic representative Dr. F. Jaquet, Head Division Clinical Trials</li><li>• Regulatory workshop on experiences with the implementation of eCTD at Swissmedic Swissmedic representatives Dr. C. Zerobin Kleist, Case Manager and Dr. S.P. Järmann, Business Project Manager</li></ul> <p>SwAPP members can find the presentations and pictures of this event in the SwAPP Filespace and Gallery, if you log in with your personal username and password under <a href="http://www.swapp.ch">www.swapp.ch</a> and go to <b>MySwAPP</b>.</p>

	<p>The panel discussion about non-interventional trials was very interactive and showed that there is still room for clarification to simplify and harmonize the (legal) process for all involved parties. A first step is taken - the discussion was very open and constructive. SwAPP is ready to support the next step and we therefore invite all interested SwAPP members and other stakeholders to contact SwAPP in order to organize an open platform to further discuss that topic. Please send an email to <a href="mailto:swapp@swapp.ch">swapp@swapp.ch</a> if you are interested to join such a discussion. SwAPP will then facilitate the organisation of a follow-up event with a smaller group of stakeholders.</p> <p>Please note: next year the SwAPP Exchange Expertise Workshop will take place on <b>03.03.2011 at the Hotel Allegro / Kursaal in Berne.</b></p> <p>We apologize that this year's meeting room was too small – the number of participants was much higher than expected.</p>
<p><b>SwAPP for SwAPP</b></p>	<p>In this issue, we are happy to publish a contribution from <b>Julia Djonova, Head of Unit Transplants Inspectorates, Swissmedic.</b></p> <p><b>Swissmedic's tasks with regard to standardised transplants</b></p> <p>When the Swiss Law on Transplantation came into force on 2 July 2007, products that are manufactured from organs, tissues or cells of human or animal origin that can be standardised, or for which the process can be standardised (standardised transplants, products from cell therapy, tissue engineering or genetically modified ex-vivo) came under the Law on Therapeutic Products and are considered to be medicinal products. To be able to carry out the tasks defined by the law, a new Transplant Unit has been created within Swissmedic. It consists of specialists with specific training and know-how that permits them to carry out the necessary work in this highly innovative field. The unit is responsible for carrying out scientific evaluations within the framework of the procedures for authorising the placing of these products on the market and for granting licenses (manufacturing, wholesaling, dispensing and import / export). Based on the transitional provisions stipulated by the law, a number of products can be found on the market, and the corresponding authorisation procedures are currently in progress.</p> <p>The unit is also responsible for the notification of clinical trials and for GCP, GMP and GDP inspections relating to these products. The first notifications of clinical trials with transplant products and GCP inspections have already been carried out. In addition to firms manufacturing these products, various hospitals are planning to use these standardised transplant products, are carrying out clinical trials, or are currently using them. It should be stressed that the GCP requirements are applicable to all products (Ordinance on Clinical Trials, Oclin, ICH GCP), but the differences compared to "conventional" medicines should be noted. Given the fact, for example, that these trials are generally of the "first in man" type and that the product used is obtained by means of a highly specific manufacturing process that can determine its safety and effectiveness, an</p>

	<p>in-depth evaluation of the documentation on quality but also the preclinical sections and the clinical experience to date (if available) is usually carried out. The documents in question should be submitted to Swissmedic within the framework of a notification. Certain trials are in fact not always applicable (such as conventional pharmacokinetic ones), but the information relating to the manufacturing, the cancerigenous or immunological potential, the potential for migration and cell proliferation or the secretion of biologically active substances, functionality, and cell viability, are aspects that are usually assessed depending on the case, the type of standardised transplant and the indication.</p> <p>Handling a notification request is often a challenge for the Transplant Unit, but also for the professionals who submit it. Several of the products in question have been on the market for years, but because a limited number of patients have been treated with them, for example, the appropriate documentation is not available. The professionals are therefore faced with the problem of finding the appropriate preclinical model or fulfilling the GMP requirements for which the corresponding experience, traditions or possibilities for application are often lacking. For this reason, the documentation is often rudimentary and does not always permit an evaluation that can guarantee that the product is completely safe. This means that the patients are exposed to various risks. Frequently faced with the above-mentioned problems such as the impossibility for a hospital to fulfil the manufacturing criteria, the lack of preclinical studies, inappropriate studies, or simply the fact that the definition / classification of a product as a transplant or transplant product can be difficult, Swissmedic is fully aware that the issue is a highly complex one. One of the Transplant Unit's priorities is thus to provide support for the sectors concerned regarding their efforts to fulfil the requirements stated in the corresponding rules, while taking into account the specificity of the products and developments on an international level. With this in mind, Swissmedic has drawn up various documents that can be found under <a href="http://www.swissmedic.ch">http://www.swissmedic.ch</a> – Transplant products (some in French and German only). Further documents that particularly concern clinical trials will be added shortly. Moreover, the Transplant Unit is always available to reply to questions or to discuss problems arising during a scientific advice process or a clarification meeting.</p>
<p><b>Events</b></p>	<p>We would like to draw your attention to a very special event:</p> <p><b>1st Symposium and Inauguration Swiss Clinical Trial Organisation (SCTO) Clinical Research in Switzerland Wednesday, June 02, 2010 Centre Hospitalier Universitaire Vaudois (CHUV), Lausanne</b></p>

	<p>For further information: <a href="http://www.scto.ch/de/agenda/Symposium.html">http://www.scto.ch/de/agenda/Symposium.html</a></p>
<p><b>Homepage News and Tipps</b></p>	<p>We are pleased with the features our new homepage offers. We would like to emphasize again that as a SwAPP member, you receive a personal User ID and Password. This allows you to login on <a href="http://www.swapp.ch">www.swapp.ch</a> at the top right corner of the page.</p> <p>Once logged in, you have access to <b>MySwAPP</b>. Here you can fill in and edit your profile under <b>My Profile</b>. We would like to encourage you to update your profile and publish it for other SwAPP members.</p> <p>You also have access to <b>All Profiles</b>, where you can see the profiles of other SwAPP members.</p> <p>Under <b>My Personal Data</b>, you can update your contact details. The information you enter here will automatically be transferred to the member database and will define how SwAPP will contact you.</p> <p>In <b>File Space</b>, you find the files SwAPP uploads for members only, for example, presentations from our events. You also find personal files here that are only visible for you, for example your yearly certificate for continuous professional education. You can also upload your own files into File Space, for example your CV or one of your own presentations, and choose to publish it for other SwAPP members.</p> <p>In the <b>Gallery</b>, you as a SwAPP member can enjoy pictures from our events, for example, the pictures from our last ExEx Workshop in Bern.</p> <p><b>Welcome to MySwAPP!</b></p>

Our Joke



An diesem Punkt sollten wir dann besser über eine Prozessoptimierung nachdenken!