

TRANSFER OF KNOWLEDGE ACTIVITIES ARTORG SEMINAR

Translating research prototype to commercial medical device product

Presenter: Dr. Robert Hellwig
Head of Product Management
Roche Diabetes Care AG

Abstract:

Apart from the realization of customer demands, commercial medical devices for human use also need to fulfill a broad range of regulatory requirements for successful market entry. The development of such a medical device is usually organized as a development project in line with a certified company-internal quality system which complies to the respective legislations (e.g. Medical Device Directive in Europe). The project includes four different phases each one closed by a milestone review.

In the analysis phase, the project scope is defined considering the technology available (research prototypes). Requirement elicitation, preparation of specifications and risk assessment take place in the feasibility phase. During the development phase, specifications are finalized and manufacturing processes defined; prototypes for verification are assembled and design verification is completed. In the last project phase before launch – the implementation phase - the design and process validation take place. Manufacturing is established and launch is prepared. Management will approve launch of the product when all regulatory requirements are met and if remaining risks are acceptable. In case of failures we start all over again.

Tuesday, Aug 7, 2012, 17:00 - 18:00

University of Bern, ARTORG Center, Murtenstrasse 50, Room F502

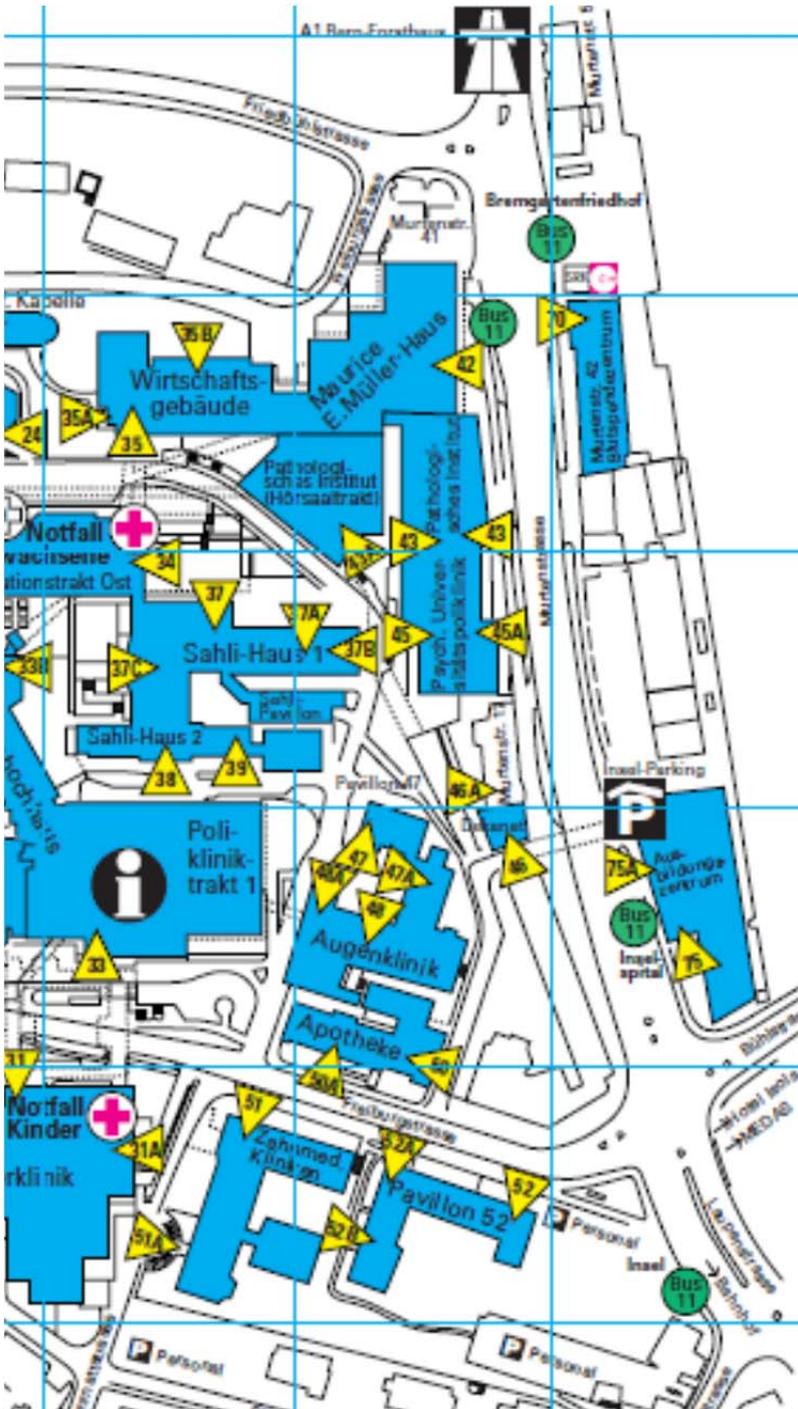
Contact:
Tel. +41 31 632 7575
Fax +41 31 632 7576
artorg@artorg.unibe.ch
www.artorg.unibe.ch
Postal address:
University of Bern
ARTORG Center
Diabetes Technology Research Group
Murtenstrasse 50 / PF44
CH-3010 Bern

GoCARB
TYPE 1 DIABETES SELF-MANAGEMENT AND CARBOHYDRATE COUNTING:
A COMPUTER VISION BASED APPROACH



GoCARB is a Marie – Curie
Industry Academia
Partnerships and Pathways
Project funded within the 7th
Programme Framework





Location:

Universität Bern
 ARTORG Center
 Murtenstrasse 50
 3010 Bern

Room F502

Public transport:

from the Main Station, Bus 11 direction
 Güterbahnhof to Bremsgartenfriedhof (4th
 stop)

By car:

Motorway A1, exit Forsthaus,
 Parking Inselspital