

“TRANSLATIONAL AND CLINICAL BIO MANUFACTURING”

(TCBM) PLATFORM

(Version 1.0)

Accepted November 08, 2018

General description: The TCBM platform is a consortium of Swiss academic teams related to bio-manufacturing units (GMP facilities).

INTRODUCTORY REMARK

The platform and the following guidelines are established in respect of the existing frame of legal and ethical rules to which the GMP facilities and teams are bound

1. FOUNDATION HISTORY

The TCBM Platform foundation was prepared from November 2016 – May 2018.

The need of a national private/public platform for cell therapy was first discussed at the “Joint Cell Therapy Meeting” hosted by SICT and SCRMB in November 2016 in Bern. Representatives of 4 academic groups considered a unifying platform potentially under the umbrella of biotechnet Switzerland (“win-win” situation). Biotechnet welcomed this initiative at its retreat in Schaffhausen January 2017 and lent support to enlarge the existing platform for “Regenerative Medicine” headed Wyss Zurich. Starting early 2017, EJM (SCRMB Platform Bern) and SMZ (Wyss Zurich) consulted on this project with representatives at the University and/or University Hospital Bern, Basel, Zurich and the SICT Foundation Geneva, as well as Fribourg.

In November 2017, the SCRMB Platform Bern became a full member of NTN-biotechnet Switzerland and the existing platform “Regenerative Medicine”, founded in 2015 by Wyss Zurich, was renamed platform for “Translational and Clinical Bio-Manufacturing” (TCBM) and is since then jointly headed by SCRMB Bern and Wyss Zurich.

As a result, on May 25th 2018, the first national Platform for “Translational and Clinical Bio-Manufacturing” (TCBM) is founded by five (5) academic member groups implicating seven (7) different universities in Switzerland as an independent entity in affiliation with biotechnet.

The founding consortium agrees (by majority member’s votes) and defines the following rules, objectives and goals as guidelines of the TCBM platform.

2. **STEERING COMMITTEE AND FOUNDING MEMBERS**

Site units	TCBM Steering committee (SC)		Founding delegates
	Delegate	Deputy	
BN - BASEL	Paul Zajac	Alessia Bottos	S. Miot, A. Wixmerten, K. Benenson
SCRM - BERN	Eliane Müller ¹	Gabriela Bearlocher	R. Aeberhard ² , C. Brunold, D. Surbek, B. Gantenbein
University / RMC - FRIBOURG	Marie-Noelle Giraud	Lavinia Alberi Auber	
SICT - Geneva, Lausanne, Bern, Lugano	Marisa Jaconi	Jean-Francois Brunet	
Wyss - ZURICH	Steffen Zeisberger ¹	Martin Kayser	

BN= Basel GMP Network; SCRM = Stem Cell Research and Regenerative Medicine; RMC = Regenerative Medicine Cluster, Fribourg; SITC = Swiss Institute of Cell Therapy; (1) Lead and Representatives biotechnet board; (2) R. Aeberhard = SCRM/TCBM office

3. **OBJECTIVES**

- a. Foster exchange and collaborations between academic groups using and operating cleanrooms including bio-manufacturing products for clinical trials.
- b. Share experience in GMP compliance and take a unified position in regulatory negotiations with Swiss notified bodies.
- c. Facilitate collaborations with the private sector including applications for bridge projects.

4. **GOALS**

- a. Organization of interactive meetings/workshops/trainings with PIs and representatives from health authorities and industry in order to further support and catalyze the manufacturing aspects of the translational process from pre-clinical towards clinical trials (according to objectives a-c).
- b. Establish and maintenance of a national public/private network fostering translational and clinical bio-manufacturing.
- c. Formation of a link including registries towards international working groups / organizations in translational and medical bio-manufacturing.

5. TCBM MEMBER SITE ORGANIZATION

Each TCBM member site is defined and constituted by a group of individual site members who:

- a. Are related to the site's GMP activities
- b. Adhere to the TCBM objectives and goals
- c. Participate in TCBM activities-meeting (directly or indirectly, at least 1/year)

Each TCBM member site is represented by a delegate and/or a deputy who

- a. Is entitled to represent his/her site organization
- b. Is involved in the organization or management of their site GMP facility/ies

6. TCBM LEADERSHIP

The foundation consortium agrees on:

- a. TCBM leadership is independent of biotechnet member ship and assumed and shared by 2 members from the TCBM SC
- b. Leadership renewal will be applied through a stepwise rotating change and approved by the steering committee.
- c. Duration of leadership: 1-3 years

As of May 2018 TCBM founder Steffen M Zeisberger (Wyss Zurich) will assume the leadership for 1 year and Eliane Muller (or another SCRM member) for 3 years.

7. TCBM STEERING COMMITTEE AND ADVISORY BOARD

The following general guidelines are:

- Steering Committee (SC) as define in chapter 2.

Composition:

- a. TCBM members (non-founding members) can apply for a seat in the SC.
- b. SC members have to be re-elected after 2 years by SC.
- c. SC is composed of maximally 7 members
- d. SC is composed by academic members only

Tasks:

- a. The SC define guidelines, tasks and competences of the TCBM platform
- b. The SC leads and decides upon the need/tasks/decision of TCBM
- c. The SC determines and implements membership applications/SC/AD members

- Advisory Board (AB)
 - a. The AB should be composed of an equilibrated number of industry/legal and other organizations/institutions members depending on the needs and requirements of TCBM
 - b. AB members can be proposed by TCBM members and are approved by SC
 - c. The AB members do not have the right to vote
 - d. The AB is maximally composed by 20 members
 - e. The AB members have to be re-elected after 2 years by SC

8. TCBM MEMBERSHIP

The membership fees are as follows:

- a. Academic Members: CHF 1'000
- b. Spin-off company members: CHF 1'500
- c. Industry Members: CHF 3'000

TCBM partners with biotechnet full member status pay exclusively CHD 10'000.- p.a. to biotechnet. Wyss Zurich and SCRM Bern are full members of biotechnet and secure the link to the association and funding opportunities for the TCBM platform. The biotechnet full members are exempt of membership fee to the TCBM platform.

9. TCBM OFFICE

For the administrative management of the TCBM platform, an office has been implemented at the University of Bern, and will be set up for the next 3 years. The official address is: SCRM/TCBM Platform office, University of Bern, DBMR, Murtenstrasse 40, 3008 Bern.

An account with the number 38 916 was opened for administrative controlling under the University of Bern, Finance Department, Hochschulstrasse 6, 3012 Bern.

Currently the office is financially supported by the University of Bern. Once the office is self-sustained, the TCBM co-lead by SCRM is no longer a prerequisite.

10. TCBM AFFILIATION

TCBM is an organizationally and financially independent platform affiliated with biotechnet.

The biotechnet association forms the organizational framework of the TCBM platform. Biotechnet is an academic network organization under the national thematic network (NTN) Swiss biotech in association with the Swiss Biotech Association (SBA) up to fall 2018.

TCBM is affiliated with biotechnet for networking, visibility and funding and represented by its full biotechnet members (currently: Wyss Zurich and SCRM Platform Bern).

TCBM is represented on the biotechnet webpage; described are the steering committee, advisory board, associate members and activities.

11. LEGAL STRUCTURE AND FINANCIAL SUPPORT

The foundation members defined that (*in the short term*) the TCBM platform will not be structured as a legal organization.

Biotechnet financially supports the TCBM platform in 2018 for administration (CHF 10'000) and meetings/events (CHF 5'000).

12. SEED FUNDING

Biotechnet supports TCBM with annual grants for cooperate projects. In 2018 “seed money” of CHF 20'000.- was attributed. The seed money rules have been approved by the biotechnet board in June 2018 and should be approved by the TCBM steering committee.

13. MEETING SCHEDULE

The following TCBM yearly schedule is defined:

- a. Steering committee: 2 meeting + 2 telconf. (or by request).
- b. Scientific meetings/events: 1-3 events
- c. Cleanroom visits / workshops / training session: 1-3