CBR Biotech Strategies GmbH

The Formation of a New Biotech Development Company in Berlin

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CBR Biotech STRATEGIES

CBR International Corp.®

CBR Family of Companies

CBR Biotech STRATEGIES	• European Representation • Regulatory Consulting & Strategy • Customized Training For All Areas Of Development • Access To An Extended Network Of Bio/Pharma Professionals In The United States & Europe
C B R International Corp.®	• US Regulatory Representation • Clinical Trial Oversight • Risk Management • Process And Method Development • Quality And GXP Compliance
TruSubmit	• Electronic Publishing • Lifecycle Management • eCTD "Readiness Assessments" • Consulting To Establish Industry Best Practices • Customized Training

CBR Family of Companies

First – A Brief Introduction to CBR International Corp.

CBR International – Boulder, CO

CBR Biotech STRATEGIES

CBR International Corp.®

About CBR International Corp.

- CBR International (CBR) was incorporated in 2001 in Boulder, Colorado
- CBR is a scientifically-based product and clinical development company initially focused on approvals in the US (FDA)
- CBR is a “thought partner” with clients
- CBR staff function as part of the client teams
- CBR staff take on “acting” management roles as well as provide technical and strategic services.

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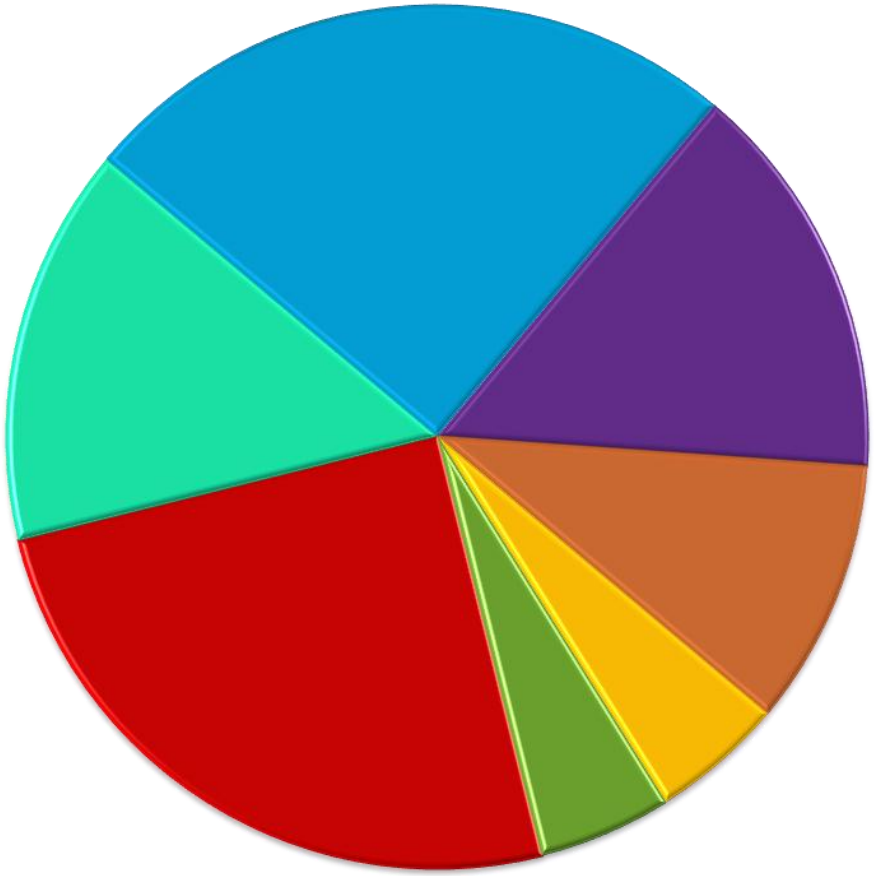
CBR International 2013 Activities



- Scientific Affairs (25%)
- Clinical Oversight (20%)
- Regulatory "Strategy" (25%)
- FDA Representation (10%)
- Quality/GMP (10%)
- Corporate Strategy (5%)
- Preclinical (5%)

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CBR International Activities

- **FDA Representation –** Serve as an Authorized Representative to FDA and take on responsibility for successful interactions with the Agency.
- **Regulatory Strategy** – Strategic and tactical planning for FDA and EU interactions.
- **Scientific Affairs** – Scientific review of processes, programs and testing. Design of pilot, validation and tech transfer programs to support regulatory filings worldwide. Comparability study experts.

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CBR International Activities

- **Clinical Strategy and Oversight** – Preparation of corporate Clinical Development Plans (CDP); Development of all clinical study documents; and RealTime™ oversight of studies.

- **Quality/cGMP** – Develop QA systems and develop cGMP compliance programs; oversee manufacturing and testing; conduct due diligence of CMOs.

- **Preclinical** - Plan and design studies; select contract laboratories; evaluate study conduct, data and final reports.

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CBR International Activities

- **Corporate Strategy** –
  - Advise executive management regarding internal and external resourcing needs and value;
  - Provide program and contractor oversight;
  - Conduct due diligence activities;
  - Plan regulatory interactions to accomplish corporate goals;
  - Present to investment groups and other interested parties on behalf of the client

CBR International Regulatory Highlights

A Typical Year For Regulatory

- Author and submit numerous (>10) original INDs
- Author and submit hundreds of IND amendments
- Act as the Regulatory Representative for >10 programs
- Plan and attend approx. 20 meetings with FDA
- Plan and attend several meetings with EMA/PEI
- Support electronic submissions for over 10 clients (TruSubmit)

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CBR Product Experience

CBR Is Experienced In A Wide Range Of Product Classes Including:

- Monoclonal Antibodies; Recombinant Protein Therapeutics (Novel; Biosimilars and Biobetters)
- Vaccines; Cell Therapies
- Small Molecules and Antibiotics
- Device and Combination Products

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Selected CBR Achievements (2011-2014)

Achievement	Agency/Center
Received FDA approval for a new drug (imaging) as the US Authorized Representative for the NDA - Mar 2014	FDA/CDER
Filed and achieved approval of 3rd Cell Therapy in US	FDA/CBER
Conducted several successful biosimilar pre-IND meetings prior to and after publication of FDA guidance	FDA/CDER
Prepared and submitted multiple INDs for initial biosimilars	FDA/CDER
Conducted successful Scientific Advice Meetings with EMA and European National Authorities	EMA + PEI
Preparation and oversight of PVP implementation	FDA and EMA

CBR International Corp.® Headquarters

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Second – A Brief Overview of TruSubmit, LLC

A new company to support CBR International and CBR Biotech Strategies clients with global electronic regulatory submissions

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TruSubmit eSubmission Services

- Electronic Publishing & Lifecycle Management
- eSubmissions Consulting
- Customized Training
- Electronic Publishing System Implementation Services

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TruSubmit

TruSubmit Services and Benefits

- TruSubmit utilizes ***cutting-edge software solutions*** to deliver compliant and timely eSubmission documents.
- TruSubmit employs ***regulatory and eSubmission experts*** to effectively navigate eSubmission complexities.
- TruSubmit provides ***tailored services*** to meet client needs.
- TruSubmit has ***global filing capabilities*** to seamlessly manage ***multi-country*** eSubmissions and management of the document lifecycles.

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TruSubmit

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Finally – An Introduction to the
Newest Company,
CBR Biotech Strategies GmbH

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CBR Biotech Strategies GmbH - Berlin

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CBR Biotech Strategies GmbH - Regulatory

- As of October 2013, **CBR Biotech Strategies GmbH** provides EU Authorized Representation on behalf of clients in non-EU states
- **CBR Biotech Strategies GmbH** can file Clinical Trial Authorizations (CTA) to run EU trials and file Marketing Application Authorizations (MAA)
- **CBR Biotech Strategies GmbH** may also act as the Authorized Representative to serve as a contact point with EU member states' Competent Authorities (CA)

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CBR Biotech Strategies GmbH - Executive

- **CBR Biotech Strategies GmbH** is the “executive” company established in order to provide strategic and programmatic planning for corporate leadership.
- **CBR Biotech Strategies GmbH** provides executive training and networking to assist in the establishment of robust teams for global product development
- **CBR Biotech Strategies GmbH** works with clients to identify program needs and assists with the development of corporate strategy and outsourcing plans for each project

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Testimonial

"I've been really impressed with the quality of service provided by Germany Trade and Invest (GTAI). GTAI's level of ***support, guidance and high standards*** *were significant factors with regard to CBR Biotech Strategies GmbH quickly becoming a registered German company.*

The dedicated efforts of the GTAI Team made the foundation process a more ***efficient and cost-effective*** *one and I highly recommend* ***Germany Trade and Invest as a business partner of choice****."*

- Stephen M. Novak, Managing Director, CBR Biotech Strategies GmbH

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CBR Family of Companies

CBR Companies Do More.

- We are not simply consultants, we are an extension of **YOUR** team in global development and strategy.
- We are not just regulatory experts, we are scientists and clinicians who understand what regulatory agencies require for product development and approval.
- Everything we do is customized to **YOUR** needs with regard to your stage of development, financial planning and corporate goals.
- **CBR Biotech Strategies** provides executive strategic services and expert EU product development services

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