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CORPORATE DECK

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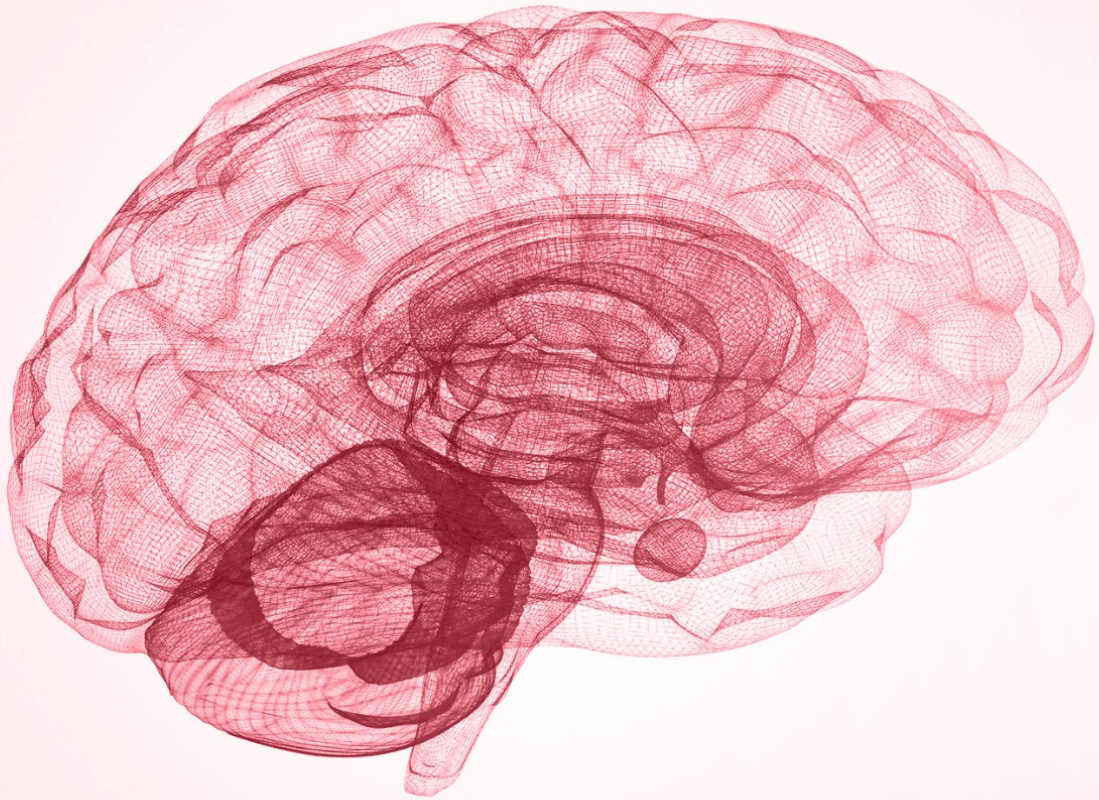

ABOUT US

Founded in 2011, **BrainLike** is a consultancy specialized in strategic solutions for the regulatory affairs area.

With expertise in development, production, research and control of medicines, cosmetics and health products, our service portfolio goes far beyond the preparation, submission and maintenance of Marketing Authorizations with Brazil Regulatory Authority - Anvisa, we work with transformation.

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- Our **vision** is to build together a new reality for the regulatory areas, optimizing operations and developing strategies and solutions for growth, improvement and adaptation to the future.

- Our **mission** is to always seek the best regulatory path to meet each company and project in a personalized way.

- It is in our **DNA** Transformation, Partnership, Collaboration and Diversity practices.

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MEET THE TEAM

BrainLike is recognized for its leadership in process transformation, incorporating more agility and efficiency into clients' regulatory businesses.

Denise Ricardo
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OUR SERVICES

REGULATORY OPERATION

- Gap Analysis
- DIFA & CADIFA (API)
- Marketing Authorization applications
- Life Cycle management.
- MA transference
- GMP

REGULATORY INTELLIGENCE

- Daily clippings and market monitoring
- Regulatory performance reports
- Evaluation of trends

CLINICAL OPERATION

- Clinical Drug Development Dossier (DDCM)
- Specific Clinical Trial Dossier(DEEC)
- Annual Safety Reports
- Evaluation of Clinical Data

REGULATORY STRATEGY

- Due Diligences
- Regulatory Writing
- Training and capacitation
- Road-maps for new business
- Hosting and partnership

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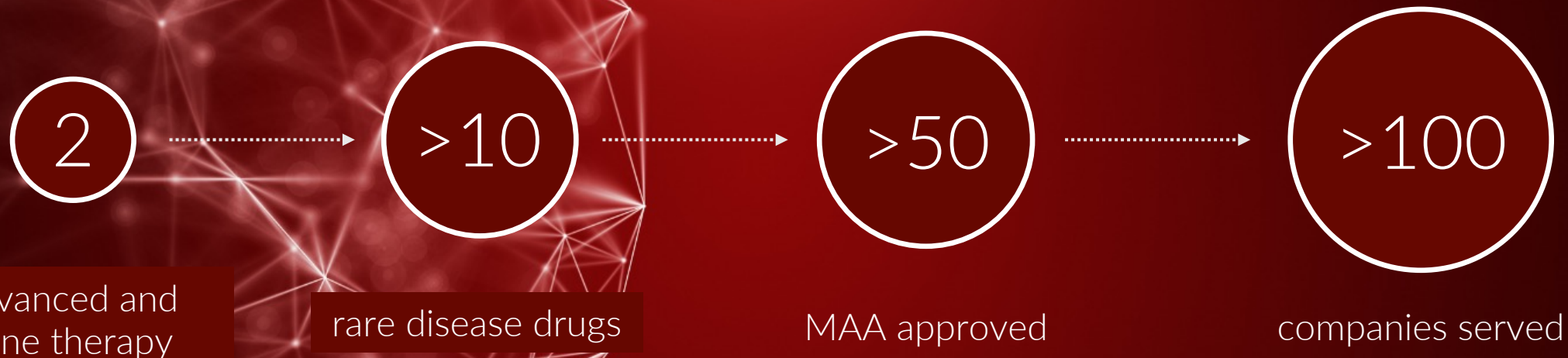
BRAINLIKE IN NUMBERS



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MARKETING AUTHORIZATION

Evaluation, preparation and assembly of dossiers for marketing authorization approval, renewals and post-approval variations of:

- Pharmaceutical Active Ingredients (APIs)
- Synthetic and Semi-Synthetic drug products
- Biological products
- Orphan Diseases
- Advanced Therapies
- Cannabis products
- Specific products
- Cosmetics
- Medical devices

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REGULATORY STRATEGY

Strategic support and conduction of:

- Due Diligences
- Gap Analysis
- Regulatory Intelligence
- GMP, audit & certification
- Road-maps for new business
- Scientific support for clinical trials
- Hosting and partnership

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TRAINING

In-company and online workshops:

- Regulatory Strategy
- Analytical Validation
- Process Validation
- Stability and Forced Degradation
- Post-approval variations
- CTD as per Anvisa's Guide n°24'2019
- Biologic Products
- DIFA &CADIFA (APIs)

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