# COMPLIFE

SCIENTISTS BEHIND WELLNESS

MEDICAL DEVICES

# FULL-SERVICE FOR COMPLIANCE

## PRE-MARKET STRATEGY

R&D SUPPORT & USABILITY
REGULATORY STRATEGY
TRAINING

## RISK MANAGEMENT

RISK MANAGEMENT PLAN & REPORT
PROCESS VALIDATION
QMS AND GMP

## SAFETY EVALUATION & CLINICAL TRIAL

TESTING AND DATA EVALUATION
CLINICAL TRIAL

## MARKET ACCESS & POST-MARKET

PRODUCT DOCUMENTATION
REGISTRATIONS
LOCAL REPRESENTATIVE
PMS

## MEDICAL COMMUNICATION

ADVERTISING
MEDICAL WRITING

# PRE-MARKET STRATEGY

- **RESEARCH & DEVELOPMENT**
- **REGUALTORY STRATEGY**
- **TRAINING**

WE GUARANTEE AN **EXECUTIVE CONSULTING SERVICE** AIMED AT IDENTIFYING AN EFFECTIVE BUSINESS STRATEGY, PROVIDING KNOW-HOW, ASSISTANCE AND TRAINING TO ACHIEVE YOUR GOALS IN COMPLIANCE WITH REGULATIONS WHILE OPTIMIZING TIME AND RESOURCES.

# RISK MANAGEMENT

- **RISK PLAN AND REPORT**
- **PROCESS VALIDATION**
- **QMS AND GMP**

WE FORMULATE A **SAFETY STRATEGY**, EVALUATING THE RISKS RELATED TO THE PRODUCT AND THE PROCESS THROUGHOUT THE ENTIRE LIFE CYCLE; WE THEN SUGGEST A PLAN OF INTERVENTION AND SAFETY MAINTENANCE IN ACCORDANCE WITH EUROPEAN AND INTERNATIONAL STANDARDS.

# SAFETY EVALUATION & CLINICAL TRIAL

- **TESTING AND DATA EVALUATION**
- **CLINICAL TRIAL**

WITHIN OUR **CERTIFIED LABORATORIES** WE SCIENTIFICALLY DEMONSTRATE THE SAFETY, TOLERABILITY AND ALSO THE EFFECTIVENESS OF YOUR MEDICAL DEVICES.

# MARKET ACCESS & POST-MARKET

- **PRODUCT DOCUMENTATION**
- **REGISTRATIONS**
- **LOCAL REPRESENTATIVE**
- **POST-MARKET SURVEILLANCE**

WE FORMULATE A **REGULATORY STRATEGY** TO ALLOW THE ENTRY OF THE MEDICAL DEVICE IN THE TARGET MARKET AND WE SUPPORT OUR CLIENT IN ALL THE NECESSARY ACTIONS TO MAINTAIN ITS PRESENCE OVER TIME.

# MEDICAL COMMUNICATION

- **MEDICAL WRITING**
- **ADVERTISING**

WE CAN WRITE MEDICAL - SCIENTIFIC PAPERS AND PROVIDE SUPPORT IN THE **COMMUNICATION OF INFORMATION** RELATED TO THE MD, TO PROMOTE THE PRODUCT TO THE FULLEST, IN COMPLIANCE WITH THE RULES OF THE SPECIFIC MARKET.

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**UNIQUE REFERENCE SPECIALIZATION GLOBAL EXPERTISE**

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