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Regulatory Affairs in Life Science



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ENABLING AND PROMOTING EXCELLENCE IN THE HEALTHCARE REGULATORY PROFESSION

What is healthcare regulatory affairs?



- Regulatory affairs developed due to government concern to protect public health and product safety and efficacy in areas such as pharmaceuticals, veterinary medicines & medical devices
- Regulatory professionals are key to the delivery of safe and effective treatments to patients



Why it matters!



Without proper regulation...



DR. J. COLLIS BROWNE'S
CHLORODYNE.
 THE ORIGINAL AND ONLY GENUINE.

CHLORODYNE is admitted by the Profession to be the most wonderful and valuable remedy ever discovered

CHLORODYNE is the best remedy known for Coughs, Consumption, Bronchitis, Asthma.

CHLORODYNE effectually checks and arrests those too often fatal diseases—Diphtheria, Fever, Croup, Ague.

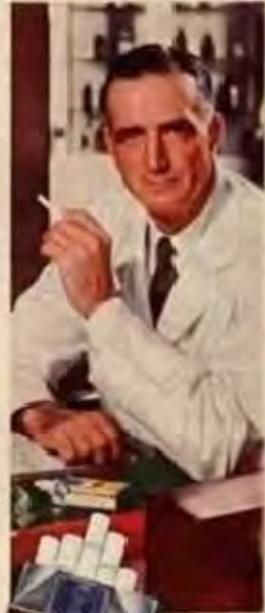
CHLORODYNE acts like a charm in Diarrhoea, and is the only specific in Cholera and Dysentery.

CHLORODYNE effectually cuts short all attacks of Epilepsy, Hysteria, Palpitation, and Spasms.

CHLORODYNE is the only palliative in Neuralgia, Rheumatism, Gout, Cancer, Toothache, Meningitis, &c.

According to repeated nationwide surveys,

**More Doctors
Smoke CAMELS
than any other
cigarette!**



Doctors in every branch of medicine were asked, "What cigarette do you smoke?" The brand named most was Camels!

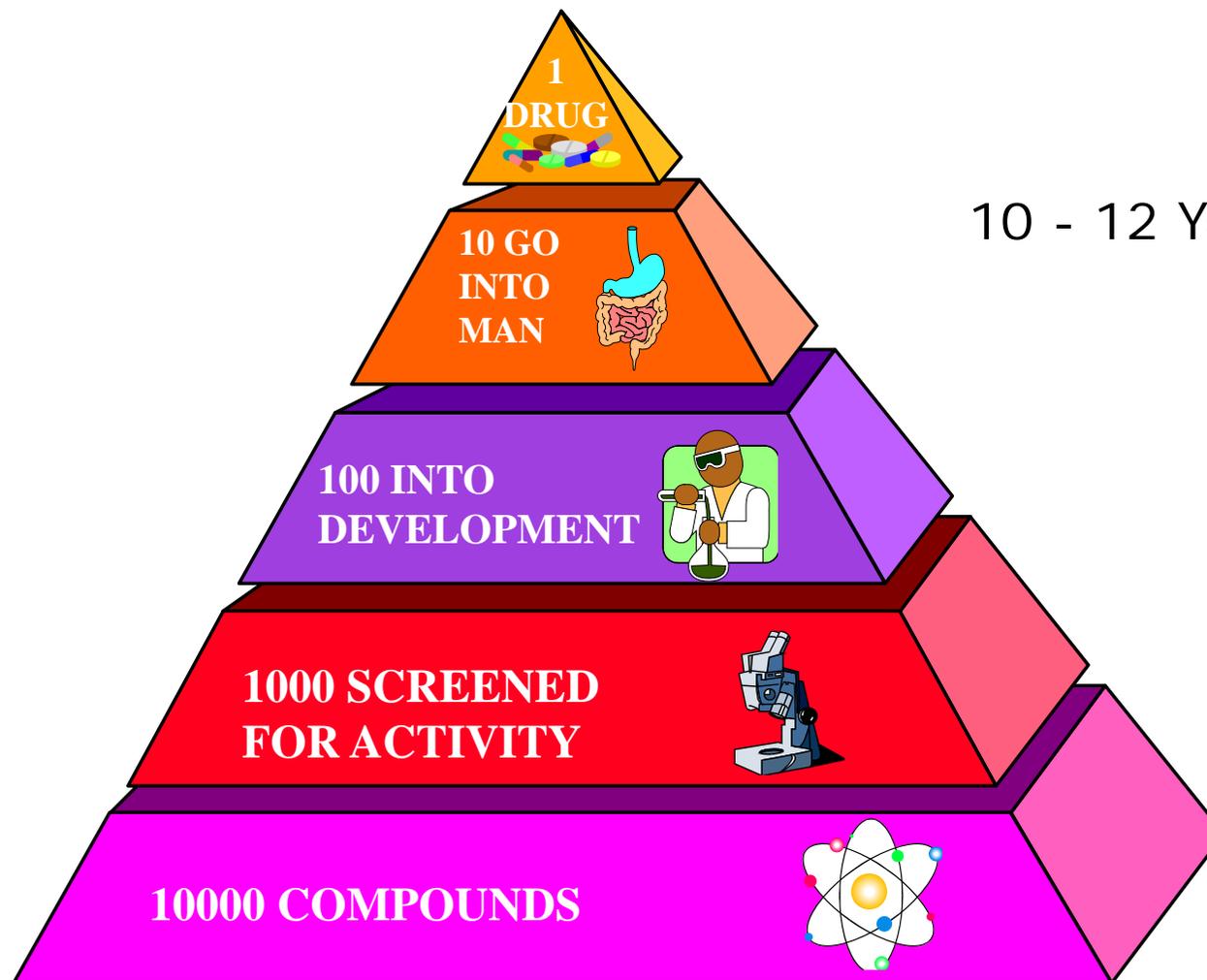
You'll enjoy Camels the most because they always taste them. Camels have that soft, buttery, fresh, clean taste, and a flavor unexcelled by any other cigarette. Make this cigarette your standard only. Camels for 100 years and you know what Camels mean. Your taste buds will tell you there are no other nearby smokes. You'll see how profitable a cigarette can be!

THE DOCTORS' CHOICE IS AMERICA'S CHOICE!



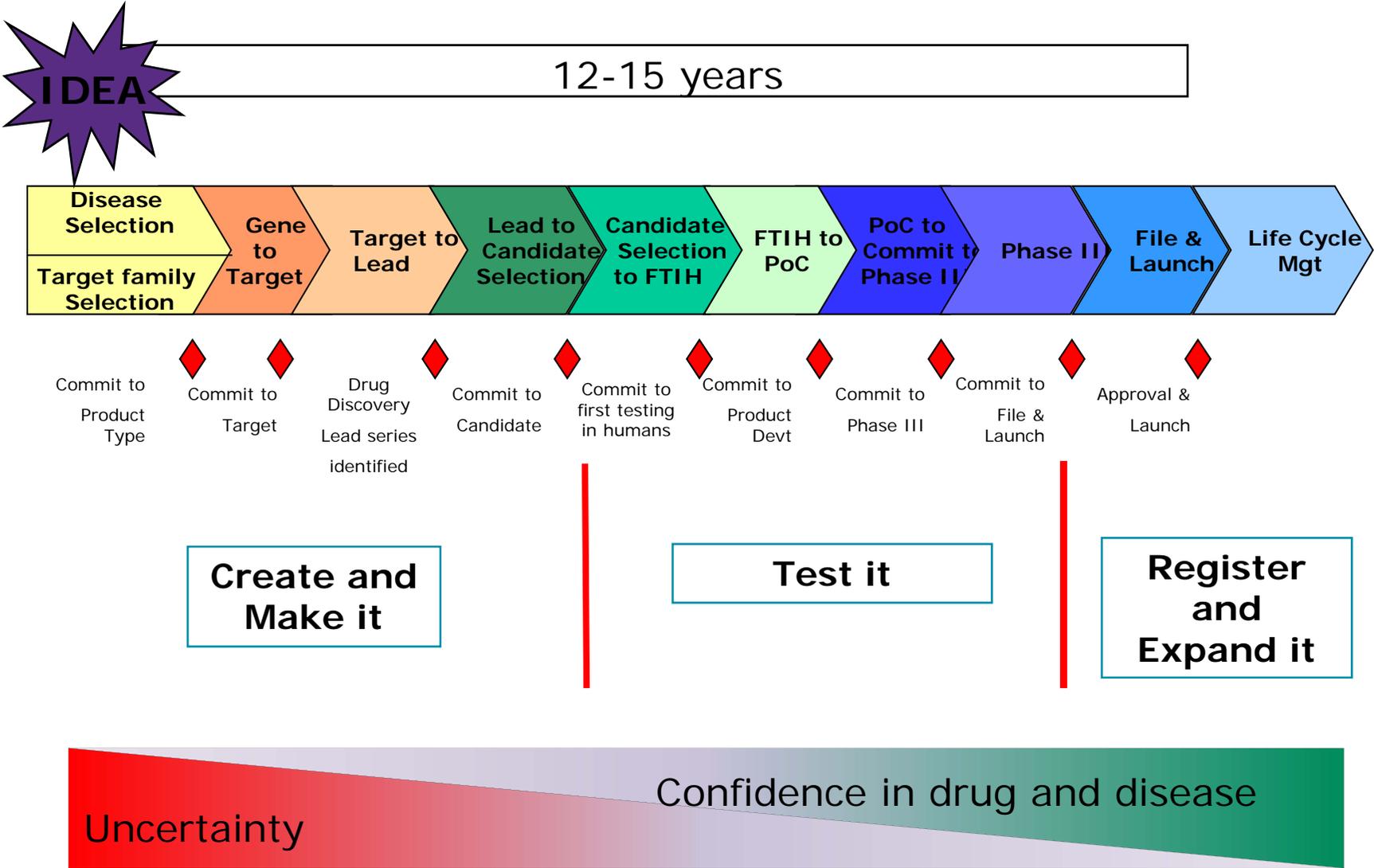
For 30 days, test Camels in your "F-Zone" (F for Throat, F for Taste)

From Compound to Drug



In practice many larger companies maintain compound libraries of many millions.

The Drug Development Process



Philosophy



THREE KEY ITEMS WHICH MUST ALWAYS BE PROVEN:

- **QUALITY**
- **SAFETY**
- **EFFICACY**



- **Increasingly the pharmaco-economics of new products is being considered.**

What regulatory affairs involves



- **Licensing, marketing and legal compliance of pharmaceutical and medical products**
- **A combination of science, legal and business – ensuring well designed and validated data with appropriate statistics and discussions**
- **Ensuring adherence and compliance with health authority guidelines and regulations**
- **Liaising internally between research, production and business development and externally with health authority personnel, inspectors and European regulators**
- **Information and intelligence gathering to try to anticipate change – keeping up to date with draft guidelines, European Directives and national laws and regulations.**

Where regulatory interfaces with other departments



What you might do!



Put together regulatory submissions

Write regulatory dossiers

Analyse data to ensure suitability for regulatory submission

Develop regulatory and development strategies for new products

Sit on a global project development team

Project manage a development or submission programme

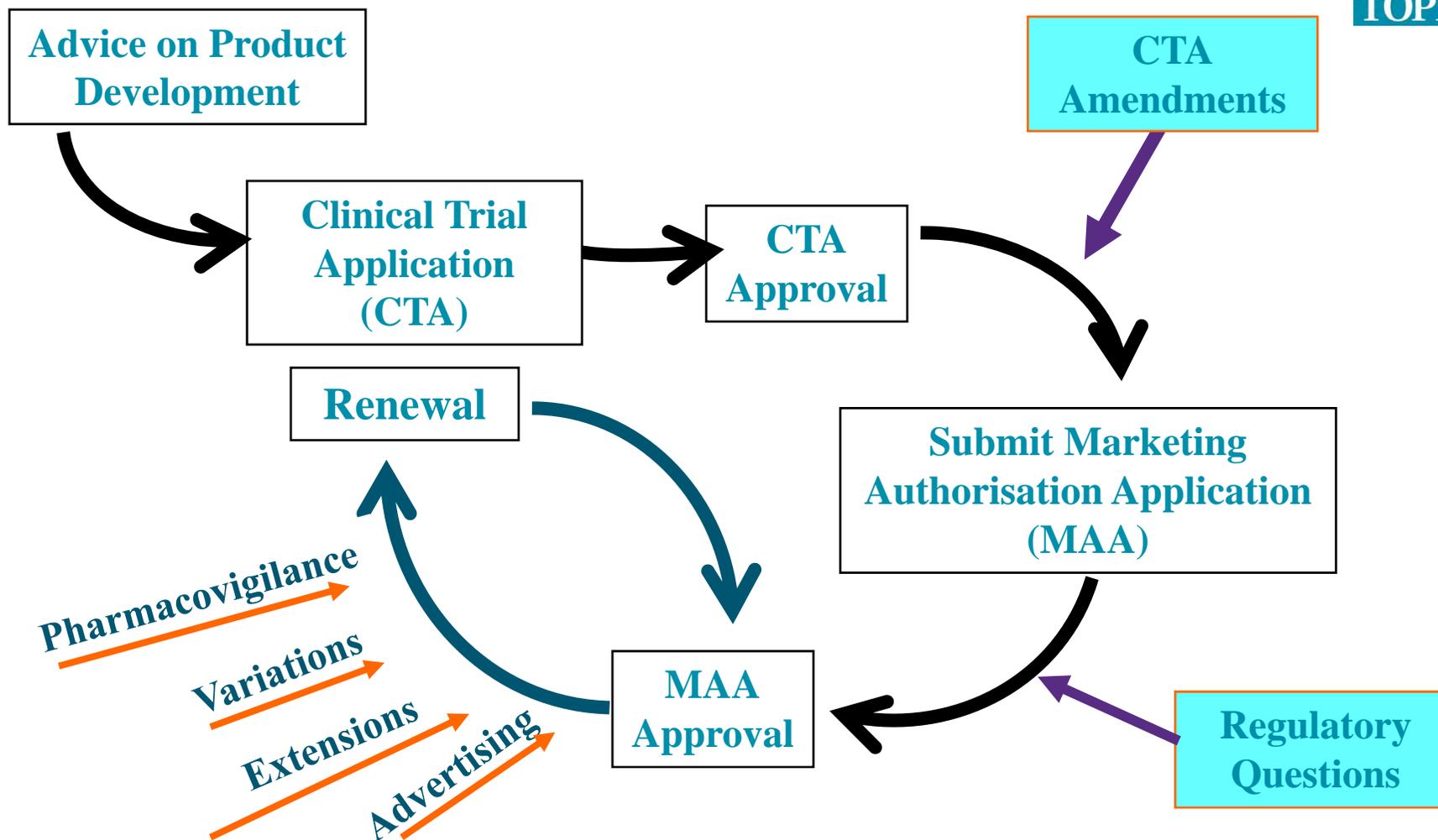
Manage products post licensing

Manage a region or territory





The Product Lifecycle



Why choose regulatory affairs?



- It is a dynamic, fast-paced environment
- It has a positive impact on society
- It interfaces with many different functions/teams
- It is a hybrid of science, business & communication
- It is a responsible job & with a practical application of science
- It recruits from diverse academic/industrial science backgrounds
- There are opportunities to work in many different business areas, eg medical devices, active ingredients, biopharmaceuticals

PLUS:

- Good opportunities to progress & develop
- Potential for international travel & flexible working conditions (hours/locations, etc)
- Opportunities to specialise (pharmaceuticals, compliance, operations, publishing, consultancy)

What do I need to become a regulatory professional?



A scientific background (usually pharmacy, chemistry or biological sciences)

- **Skills include:**

- Interest in a wide range of scientific disciplines
- Excellent written and verbal communication skills
- Team working and negotiation skills
- Problem solving – creative thinking
- Project management
- Attention to detail
- Flexibility and ability to work in a dynamic and constantly changing environment

A knowledge of legal frameworks, processes and procedures can be learned!

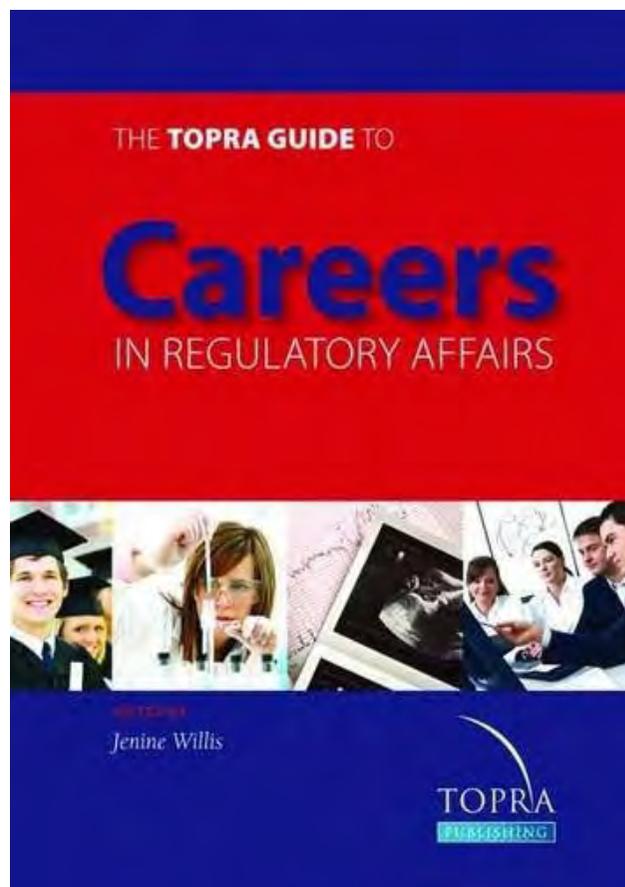
Getting started...



- **Look for work experience opportunities – in a healthcare related setting if possible**
- **Build a good, relevant and accurate CV**
- **Look out for graduate training schemes and apprenticeship opportunities**
- **Join TOPRA as a student member!**



To find out more go to
www.topra.org/careers



This careers guide is available on Amazon, but is free for student members.

Career long approach to professional development



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