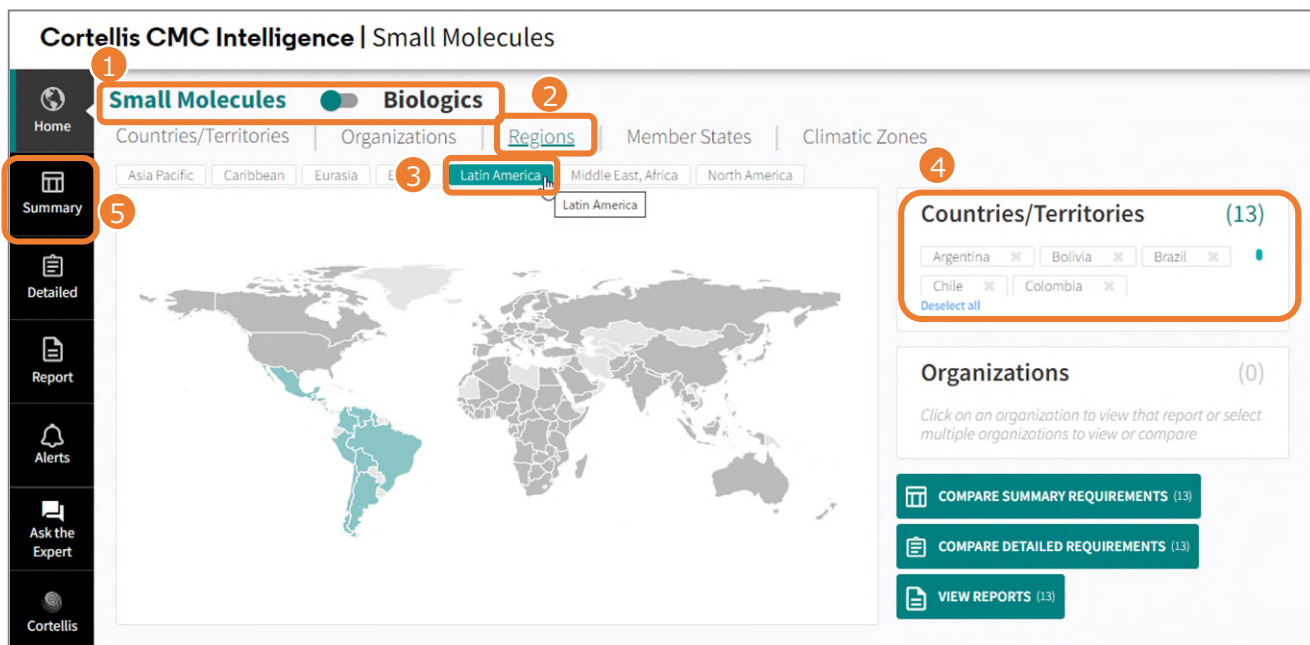


# Cortellis CMC Intelligence

## 複数の国のCMC要件の比較表の活用

この資料では、複数の国のCMC規制要件を比較できる“Summary”へのアクセス方法をご案内します。  
ここではLatin America諸国の規制要件の調査例をお示します。

1. 画面上部の“Small Molecules”と“Biologics”の切替ボタンを使用し、調査対象の製品カテゴリを指定します。  
(両モジュールへのアクセス権をお持ちのユーザー様のみ)
2. “Regions”メニューをクリックします。
3. 選択可能な地域が表示されたら“Latin America”をクリックします。
4. 選択された国は地図上で表示が緑色に変わります。また、画面右上の“Countries/Territories”セクションに、選択中の国名が表示されます。  
国名の右側の“X”ボタンをクリックすると選択を解除できます。また、“Deselect all”をクリックすると全ての国の選択が解除され、画面が初期状態に戻ります。
5. 画面左側のナビゲーションバー上の“Summary”をクリックしてコンテンツを表示させます。



The screenshot displays the Cortellis CMC Intelligence interface for Small Molecules. The interface includes a top navigation bar with tabs for "Small Molecules" (selected) and "Biologics". Below this, there are tabs for "Countries/Territories", "Organizations", and "Regions". The "Regions" tab is active, showing a list of regions including "Latin America", "Middle East, Africa", and "North America". The "Latin America" region is highlighted in green. On the right side, the "Countries/Territories" section shows a list of countries (Argentina, Bolivia, Brazil, Chile, Colombia) with a count of (13). Below this, the "Organizations" section shows a count of (0). At the bottom, there are three buttons: "COMPARE SUMMARY REQUIREMENTS (13)", "COMPARE DETAILED REQUIREMENTS (13)", and "VIEW REPORTS (13)". On the left side, there is a vertical navigation bar with buttons for "Home", "Summary" (highlighted), "Detailed", "Report", "Alerts", "Ask the Expert", and "Cortellis".

## Summary画面

- “Summary Requirements”のメニューから、閲覧したい比較表のトピック名をクリックします。  
以下の例では“CMC Requirements”カテゴリの“Long term Stability - Drug Products”を選択しています。

**Cortellis CMC Intelligence | Small Molecules**

My selection (13)

Summary

Requirements

CMC Requirements

Nomenclature

Compendial standards

Details of manufacturer

Quality documentation

Impurities

Physicochemical and biological properties

Accelerated Stability - Drug Substance

Long-term Stability - Drug Substance

Accelerated Stability - Drug Product

Long-term Stability - Drug Product

Marketing Authorization Application

Long-term Stability - Drug Product

My selection	Storage conditions	Submission type	Climatic Zone	Temperature (°C)	Relative Humidity (%)	Real time submission
Argentina	General case		II	25±2	60±5	
Bolivia	General case	N/A	IV b	30±2	75±5	
Brazil	General case - semi-permeable container	Generic	IV b	30±2	35±5	
Brazil	General case - semi-permeable container	NCE	IV b	30±2	35±5	
Brazil	Freezer	Generic		-20±5		
Brazil	Refrigerator	Generic		-5±3		
Brazil	Freezer	NCE		-20±5		

- “My Selection”メニューを開くと、Home画面で選択したLatin Americaの国名が表示されます。特定の国名をクリックすると、当該国の詳細要件を確認できる“Report”画面に移行します。  
以下の例では“Brazil”を選択しました。

**Cortellis CMC Intelligence | Small Molecules**

My selection (13)

Argentina

Bolivia

Brazil

Chile

Colombia

Costa Rica

Guatemala

Guyana

Honduras

Mexico

Report

**Cortellis CMC Intelligence | Small Molecules**

My selection (13)

Key Facts

Key Requirements

Procedures

Detailed Requirements

Sources

Change History

Brazil

Key Facts

**Brazilian Health Regulatory Agency (ANVISA)** is responsible for regulating and implementing controls relating to production and commercialization, import, export of all the products subjects to the Brazilian Sanitary Surveillance System, including pharmaceutical products (API, FPP), cosmetics, food supplements, devices, tobacco and sanitizer products and other products that may products involving the possibility of health risk. ANVISA is structured into 5 directories and further subdivided into several management areas, which are defined in RDC 255/2018 and its revisions. The registration of medicinal products is responsibility of the General Office for the Evaluation of Medicinal products (GGMED). The analysis of the documentation related to the Pharmaceutical Technology of a registration process for a new, generic or similar medicinal product is accredited by the Office Responsible for the Evaluation of Technology Quality Assessment of for the Registration of Synthetic Medicinal Products (GQRMED).

ANVISA in the past decade has expended its international participation in bilateral, regional and multilateral forums that discuss regulatory harmonization and convergence processes. ANVISA became a regulatory member of ICH in November 2019. ANVISA was elected to be part of ICH's Management Committee. With its participation in ICH, ANVISA is contributing some of the ICH guidelines, as the medical dictionary MEDRA and the Common Technical Document (CTD) (see Guide 24 from August 2019). ANVISA has also applied to become part of the ICH Co-operation Scheme (PIC/s) which has lead to the review of the Brazilian Good Manufacturing Practices (GMP) with the issuance of RDC 301 and a series of normative instructions that details procedures for the registration of medicinal products (see IN 35 to 48). Brazil has also been an active member of MERCOSUR, as Argentina, Paraguay, Uruguay, Venezuela (suspended). The MERCOSUR purpose is free trade and the fluid movement of goods, people, and currency; and is now a full customs union and a trading block. Even though ANVISA works on convergence of regulations with the Health Authorities that are part of Mercosur, to date country specific registration is required in each market and there are no reliance mechanisms in place among the countries;

選択した国の  
“Report”画面に遷移します