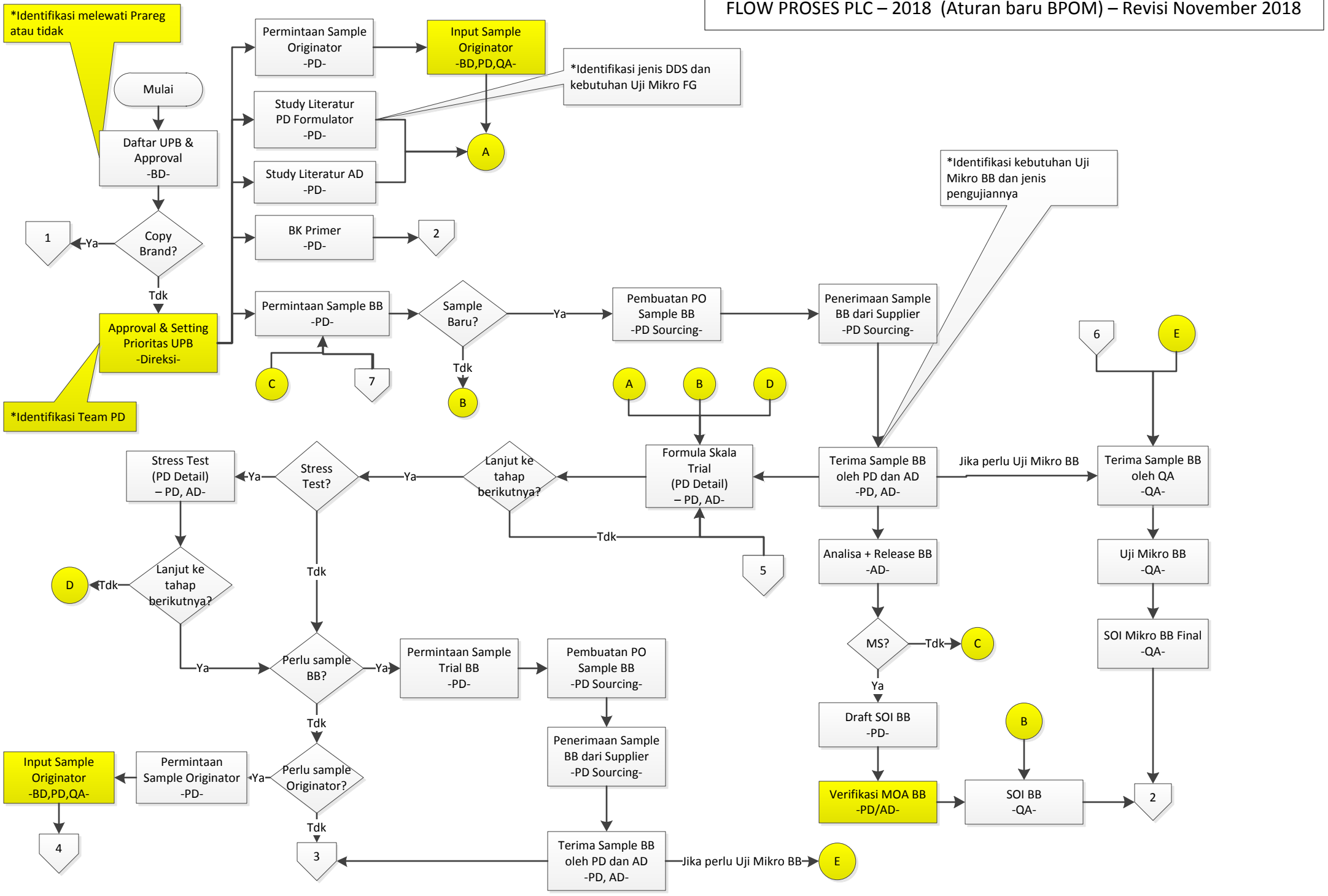
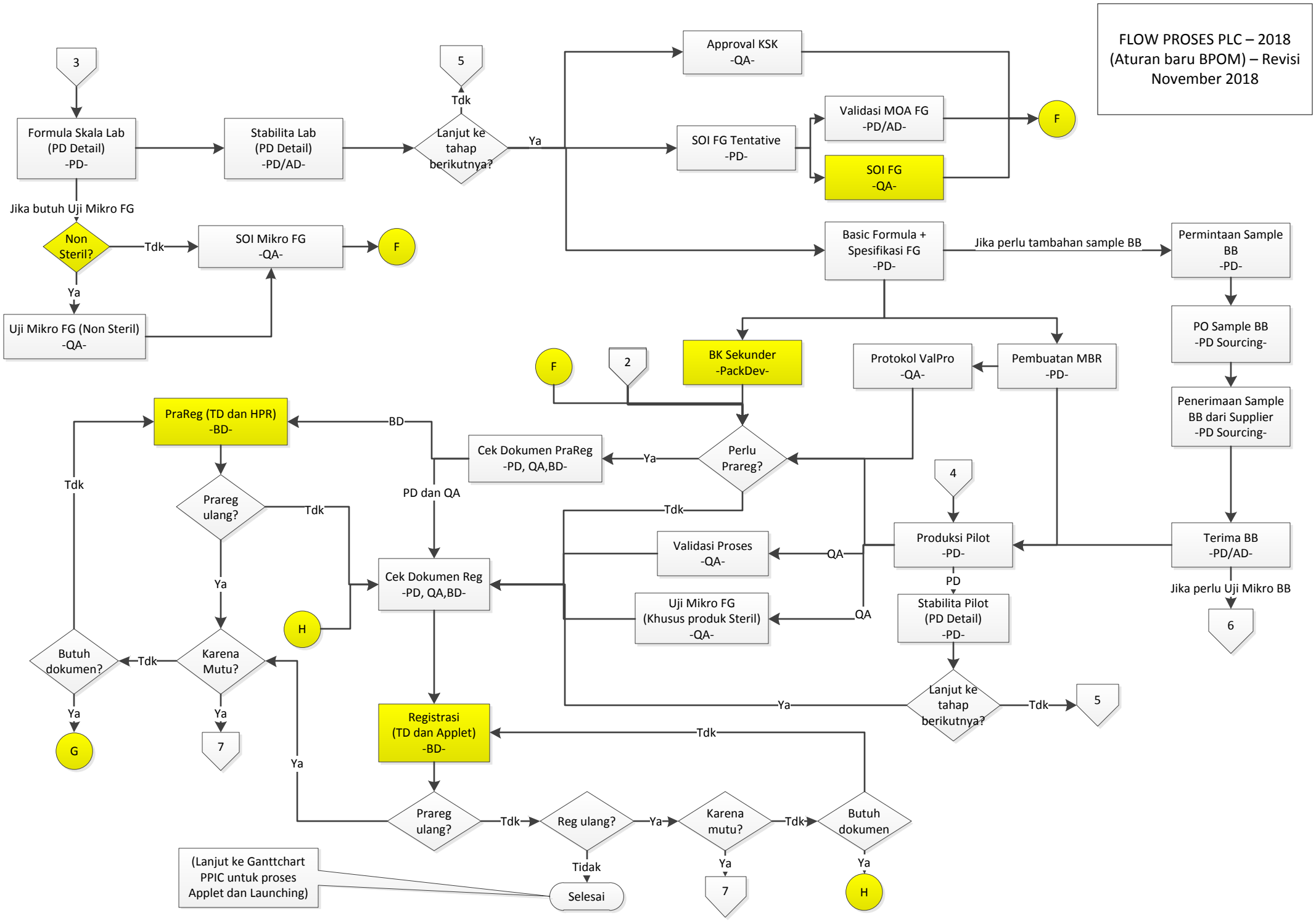
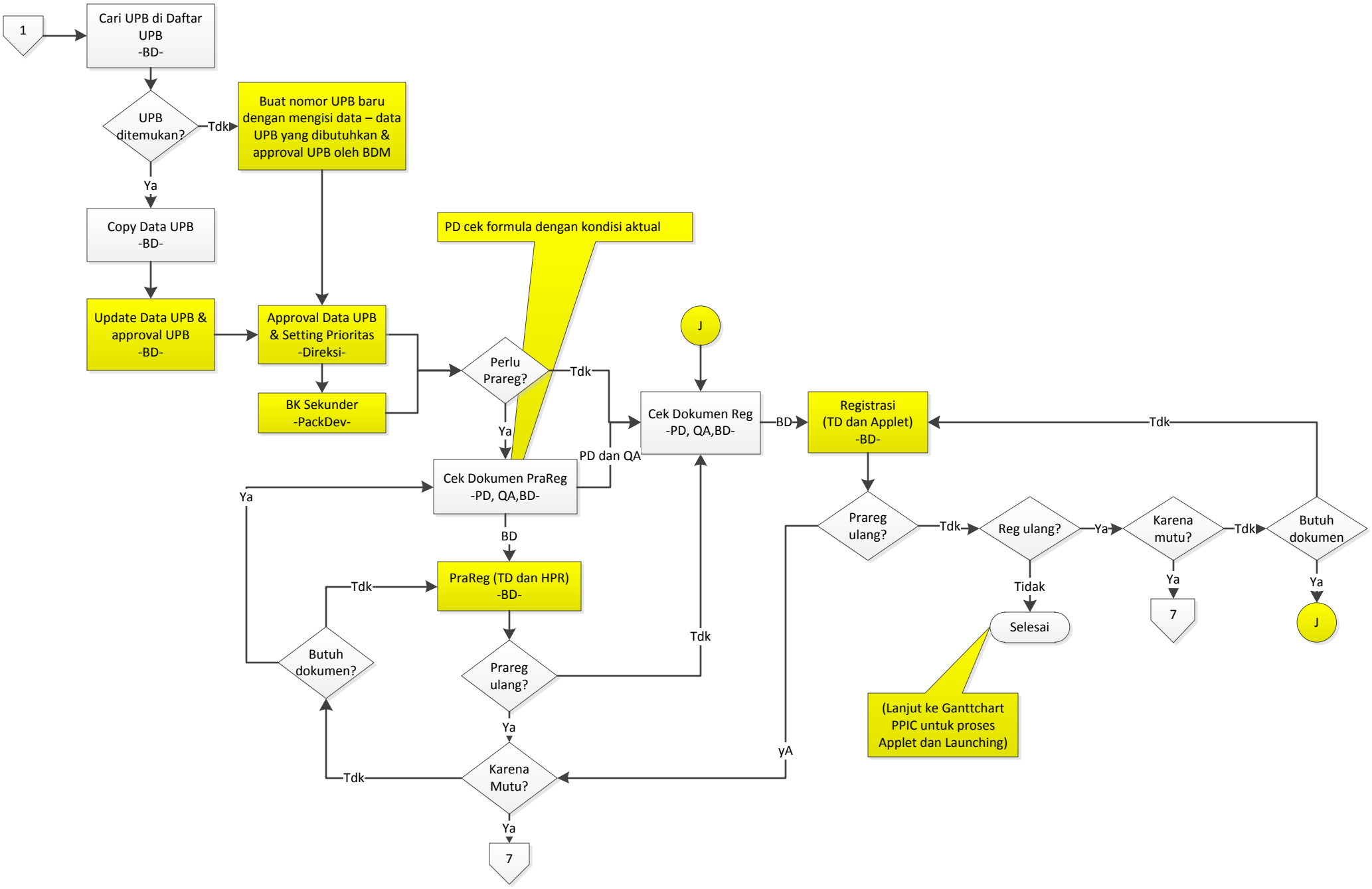
FLOW PROSES PLC – 2018 (Aturan baru BPOM) – Revisi November 2018




FLOW PROSES PLC – 2018
(Aturan baru BPOM) – Revisi
November 2018
3
Formula Skala Lab
(PD Detail)
-PD-
Stabilita Lab
(PD Detail)
-PD/AD-
5
Tdk
Lanjut ke
tahap
berikutnya?
Ya
Approval KSK
-QA-
SOI FG Tentative
-PD-
Validasi MOA FG
-PD/AD-
SOI FG
-QA-
F
Jika butuh Uji Mikro FG
Non
Steril?
Tdk
SOI Mikro FG
-QA-
F
Ya
Uji Mikro FG (Non Steril)
-QA-
Basic Formula +
Spesifikasi FG
-PD-
Jika perlu tambahan sample BB
Permintaan Sample
BB
-PD-
PO Sample BB
-PD Sourcing-
Penerimaan Sample
BB dari Supplier
-PD Sourcing-
Terima BB
-PD/AD-
Jika perlu Uji Mikro BB
6
F
2
BK Sekunder
-PackDev-
Protokol ValPro
-QA-
Pembuatan MBR
-PD-
PraReg (TD dan HPR)
-BD-
BD
Cek Dokumen PraReg
-PD, QA,BD-
Ya
Perlu
Prareg?
Tdk
PD dan QA
Prareg
ulang?
Tdk
Ya
4
Produksi Pilot
-PD-
Validasi Proses
-QA-
QA
PD
Stabilita Pilot
(PD Detail)
-PD-
Uji Mikro FG
(Khusus produk Steril)
-QA-
QA
Cek Dokumen Reg
-PD, QA,BD-
H
Tdk
Butuh
dokumen?
Tdk
Karena
Mutu?
Ya
Ya
G
7
Ya
Lanjut ke
tahap
berikutnya?
Tdk
5
Registrasi
(TD dan Applet)
-BD-
Tdk
Prareg
ulang?
Tdk
Reg ulang?
Ya
Karena
mutu?
Tdk
Butuh
dokumen
Tidak
Selesai
Ya
7
Ya
H
(Lanjut ke Ganttchart
PPIC untuk proses
Applet dan Launching)

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(Aturan baru BPOM) – Revisi November 2018